Totale heupprothese (THP)

Deze richtlijn is tot stand gekomen op initiatief van Nederlandse Orthopaedische Vereniging

Inhoudsopgave

Startpagina - Totale heup prothese (THP)

Waar gaat deze richtlijn over?
Deze richtlijn omvat wat volgens de huidige maatstaven de beste zorg is voor patiënten die in aanmerking komen voor een totale heupprothese. In de richtlijn komen de volgende onderwerpen aan de orde:

- Indicatiestelling van een totale heupprothese
- Operatietechnische aspecten
- Zorg rondom de operatie
- Nazorg bij een totale heupprothese

Voor wie is deze richtlijn bedoeld?
Deze richtlijn is ontwikkeld voor alle zorgverleners die betrokken zijn bij de zorg voor patiënten die in aanmerking komen voor een totale heupvervanging.

Voor patiënten
Een totale heupprothese is de vervanging van de gehele heup door een prothese. Deze prothese bestaat uit een heupkom en een steel met daarop de heupkop. Er zijn verschillende redenen om een totale heupvervanging te verrichten waarvan slijtage (artrose) en een breuk van de dijbeenhals (heupfractuur) de belangrijkste zijn.

Betrouwbare informatie over behandelkeuzes en heupprothesen is te vinden op:
Link naar Thuisarts:
https://www.thuisarts.nl/kunstheup-bijvoorbeeld-bij-artrose-van-heup/ik-overweeg-kunstheup
Link naar Consultkaart – Artrose van de Heup:
https://consultkaart.nl/wp-content/uploads/2017/01/20161219_CK_Artrose-in-de-heup.pdf
Link naar NOV website:
www.zorgvoorbeweging.nl/heup

Hoe is de richtlijn tot stand gekomen?
Het initiatief voor deze richtlijn is afkomstig van Nederlandse Orthopaedische Vereniging (NOV). De richtlijn is opgesteld door een multidisciplinaire commissie met vertegenwoordigers vanuit de orthopeden, arts-microbiologen, geriaters en fysiotherapeuten. Er is aandacht besteed aan het patiëntenperspectief door de participatie van ReumaNederland en Nationale Vereniging ReumaZorg Nederland in de werkgroep. Daarnaast is de richtlijn ter commentaar opgestuurd naar de Patiëntenfederatie en de Polyartrose Vereniging.

Status van de richtlijn
Deze richtlijn is een update van de richtlijn Totale Heupprothese (2010). De aanpassingen weerspiegelen nieuwe klinisch-wetenschappelijke ontwikkelingen op zowel operatietechnisch als zorginhoudelijk terrein. De herziene en nieuwe modules worden gepresenteerd in de Engelse taal om internationale samenwerking en uitwisseling van kennis te faciliteren; de uitgangsvragen en aanbevelingen zijn ook in het Nederlands gepresenteerd.

De volgende modules zijn herzien:

1. Indicatiestelling
2. Lagering
3. Kopdiameter
4. Benaderingswijze
5. Systemische antibiotica
6. Antibioticumhoudend botcement
7. Preoperatieve dekolonisatie
8. Routinematige follow-up

De volgende modules zijn ongewijzigd overgenomen:

1. Gecementeerd versus ongecementeerd

De volgende modules zijn verwijderd:

2. Resurfacing
3. Minimaal invasieve chirurgie
4. Maatregelen bij MRSA-dragers

De volgende modules zijn vervangen door een referentie naar andere richtlijn:

1. Hematogene besmetting
2. Preventie van veneuze trombose
3. Fysiotherapie

De volgende modules zijn niet herzien vanwege een richtlijn die binnenkort wordt verwacht:

1. Anesthesietechniek bij totale heupprothese

De volgende modules zijn toegevoegd:

1. Patient Reported Outcome Measures (PROMs)
2. Plaats en organisatie van fasttrack programma
3. Organisatie van zorg voor kwetsbare ouderen

Verantwoording

Laatst beoordeeld : 12-02-2019
Laatst geautoriseerd : 12-02-2019

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Indicaties en contra-indicaties voor een totale heup prothese (THP)

Uitgangsvraag

Wat zijn de indicaties en contra-indicaties voor een totale heupprotese bij patiënten met artrose?

Aanbeveling

Bied patiënten met artrose van de heup een totale heupvervanging aan als er sprake is van pijn en/of functieverlies, als er radiologische afwijkingen zijn die wijzen op een eindstadium van heupartrose, en als conservatieve behandeling heeft gefaald.

Een maligniteit (in de anamnese), diabetes en overgewicht zijn geen contra-indicaties.

Neem het besluit om al dan niet te opereren samen met de patiënt, nadat deze geïnformeerd is dat:

- Patiënten met diabetes of met overgewicht (BMI >30 kg/m²) een grotere kans hebben op complicaties en mogelijk minder baat hebben van de heupvervanging.
- De levensduur van het implantaat minder is bij patiënten met een maligniteit in de anamnese en bij patiënten met diabetes of overgewicht.

Overwegingen

THA is an effective and successful surgical procedure for end stage osteoarthritis of the hip when conservative treatment has failed. Recommendations about conservative treatment are described in the guideline 'Conservatieve behandeling van artrose in heup of knie'. In the early development of THA, only healthy patients with single end stage osteoarthritis underwent surgery. Nowadays patients with comorbidities are also eligible for surgery. It is questionable whether outcomes in these patients are comparable to patients without comorbidities.

In general, comorbidities are associated with higher anaesthetic risks and operative complications after THA. For comorbidities, a distinction should be made between diseases causing osteoarthritis and disorders coexisting with (primary or secondary) osteoarthritis.

In this literature analysis, comorbidities affecting the outcome of THAs were studied. The term “comorbidity” is used as a container concept to describe possible risk factors for impaired outcome (for example smoking is not a real comorbidity). In addition, one patient with a history of malignancy might have an impaired physical condition and life expectancy, while another patient might have been cured years ago and have a (nearly) normal life expectancy. The study by Jämsen (2013) concluded that in general a history of malignancy was associated with impaired survival of the hip prosthesis in patients with osteoarthritis.

Studies reporting adverse reactions, complications, survival, functional gain and pain relief after THA in patients with osteoarthritis and a history of malignancy, diabetes, obesity, who are smokers or are using immunosuppressants were selected. These factors were selected because the prevalence of these

comorbidities is increasing. Furthermore, these comorbidities influence anaesthesia and functional gain after THA.

Obese patients have higher surgical risks. A higher BMI is associated with an increased incidence of peri-operative complications and decreased functional gain after the THA (Chee, 2010; Fu, 2016; Li, 2017, Davis, 2011). Ideally, diabetes mellitus should be divided in type 1 and 2, because the duration of the disease is different in these patients. These differences have different effects on surgery. Proper control of the diabetes will diminish the peri-operative complication rate. Having diabetes was not associated with more joint infections. Moreover, the survival of the prosthesis was also not impaired Jämsen, (2013). We found no studies investigating the influence of smoking habits and the use of immunosuppressants on the defined outcomes. Only five observational studies were found (Chee, 2010; Fu, 2016; Li, 2017; Jämsen, 2013, Davis, 2011). Because of the observational design of the included studies the evidence was graded low.

Generally, studies from Joint Replacement Registries showed worse outcomes after a THA in patients suffering from avascular osteonecrosis or rheumatoid arthritis compared to patients with idiopatic osteoarthritis.

Surgeons must weigh the risks against the benefits for each patient with comorbidities individually. In the pre-operative phase, they must evaluate if there are any comorbidities that can increase the surgical risk. The life expectancy of the individual patient with a history of malignancy should be evaluated, diabetes patients must have proper control and obese patients should be advised to lose weight. To decide upon surgery the surgeon should consult other medical professionals like an anaesthesiologist or oncologist. Finally, the surgeon will discuss the possibilities with the patient and make decisions together. Option grids are useful to facilitate shared decision making.

Inleiding

Pain and loss of function, in combination with radiographic changes due to end stage osteoarthritis of the hip, are the mean reasons for total hip arthroplasty (THA).

The indication for hip replacement, which is increasing in many parts of the world, does not depend only on the incidence and prevalence of osteoarthritis, but is also influenced by other factors like the more and more active style of living in the elderly, higher life expectancy, improved outcomes of arthroplasties, changing reimbursement systems, etc. Therefore, indications for total hip arthroplasty differ around the world, and can only be given in general terms: the indication should be based on pain, loss of function, and radiographic changes after failure of conservative treatment, considering the individual contra-indications, in a shared – decision making process with the patient.

Since the population is getting older and more patients suffer from comorbidities, the question is which patients will benefit most from THA and should comorbid conditions be considered contra-indications?

Conclusies

PICO 2

Very Low GRADE	Survival of the prosthesis after total hip arthroplasty for osteoarthritis seems to be impaired in patients with a history of malignancy, compared to patients without a history of malignancy. *Sources Jämsen, (2013)*

PICO 3

Very low GRADE	There seems to be no difference in survival of the prosthesis after total hip arthroplasty for osteoarthritis in patients with diabetes compared to patients without diabetes. *Sources Jämsen, (2013)*

PICO 4

Very low GRADE	Complication rates after total hip arthroplasty for osteoarthritis seem to be higher in obese patients compared to non-obese patients. *Sources (Chee, 2010; Fu, 2016; Davis, 2011)*

Very low GRADE	Survival of the prosthesis after total hip arthroplasty for osteoarthritis seems to be lower in obese patients compared to non-obese patients. *Sources Chee, (2010)*

Very low GRADE	Functional gain after total hip arthroplastyfor osteoarthritis seems to be lower in obese patients compared to non-obese patients. *Sources (Li, 2017; Davis, 2011)*

Very low GRADE	There seems to be no difference in pain relief after total hip arthroplasty for osteoarthritis in obese patients compared to non-obese patients. *Sources (Li, 2017; Davis, 2011)*

Samenvatting literatuur

Description of studies
Five studies were included in the literature summary (Chee, 2010; Li, 2017; Fu, 2016; Jämsen, 2013, Davis, 2011).

The prospectively matched study by Chee (2010) compared THAs performed in morbidly obese patients with osteoarthritis (n=55) with a matched group of non-obese patients (n=53). Morbid obesity was defined as a BMI >40 kg/m^2 or as >35 kg/m^2 with at least one comorbidity. Participants were categorised as non-obese when their BMI was <30 kg/m^2. The participants were matched for age, gender, type of prosthesis, laterality and pre-

operative Harris Hip Score (HHS). Reported outcome measures were post-operative HHS, SF-36 scores, complication rate (superficial wound infection, deep joint infection, deep-vein thrombosis, pulmonary embolism, peri-operative mortality and dislocations) and survival (with revision surgery as endpoint) Chee, (2010).

The prospective national cohort study by Li (2017) evaluated to which extent osteoarthritis patients (n=2040) with various levels of obesity benefited from THA. The study was based on a large, prospective national cohort of patients treated with THA Li, (2017). Patients were grouped according to their pre-operative BMI as underweight or normal weight (≤24.99 kg/m^2), overweight (25.00 to 29.99 kg/m^2), obese (30.00 to 34.99 kg/m^2), severely obese (35.00 to 39.99 kg/m^2) or morbidly obese (≥40.00 kg/m^2). Adjustments were performed for baseline function and pain score, gender, age, ethnicity, household income, education, living alone, type of insurance, medical comorbidities, low back pain, number of other painful joints and surgical volume of the hospital. Reported outcome measures were physical function (Physical Component Summary (PCS) score) and pain (Hip disability and Osteoarthritis Outcome Score (HOOS score)) Li, (2017).

The observational study by Fu (2016) investigated the independent morbidity risk of malnutrition relative to obesity in patients with osteoarthritis (n=20,210) who underwent a THA. Data from the National Surgical Quality Improvement Program (NSQIP) database were used in this study. Despite the quality and prospective nature of data collection for the NSQIP, pre-operative serum albumin data were not available for a significant percentage of cases. Demographic variables, modified CCI, and obesity classifications were compared between patients with and without pre-operative albumin measurements. Propensity scores were used as a control for potential selection bias in this analysis. Patients were classified as non-obese (BMI: 18.5 to 29.9), obese I (BMI: 30 to 34.9), obese II (BMI: 35 to 39.9), or obese III (BMI >40). Reported outcome measures were 30-day complications (any complications, any major complications, wound complications, respiratory complications, blood transfusions, return to operation room within 30 days, extended length of stay (LOSS)) Fu, (2016).

The register-based study by Jämsen (2013) examined how comorbid diseases affect survival in patients with osteoarthritis (n=43,737) who underwent THA. The reported outcome measure was survival. Adjustments were performed for age, gender, year of operation, laterality of operation (unilateral, simultaneous bilateral), method of prosthesis fixation and type of operating hospital (university, central, regional or other type of hospital) Jämsen, (2013).

The observational study by Davis (2011) examined the effect of body mass index (BMI) on the medium-term outcome after THA in patients with osteoarthritis (n=1617). The reported outcome measures were dislocation, revision, duration of surgery, deep and superficial infection, HHS and SF-36. In the multivariate analysis adjustments were performed for age, gender, operating consultant, pre-operative HHS and SF-36 scores and a diagnosis of malignancy, atherosclerotic disease, cardiac disease, diabetes mellitus, osteoporosis or phlebitis Davis, (2011).

Results

PICO 1: What are the favourable and unfavourable effects of total hip arthroplasty in patients with osteoarthritis using immunosuppressants, versus patients with osteoarthritis not using immunosuppressants?

No studies were found describing the outcomes in patients using immunosuppressants compared to patients not using immunosuppressants.

PICO 2: What are the favourable and unfavourable effects of total hip arthroplasty in patients with osteoarthritis and (a history of) malignancy, versus patients with osteoarthritis and without (a history of) malignancy?
No studies were found describing complications, functional gain and pain relief in patients with (a history of) malignancy compared to patients without (a history of) malignancy.

Survival
In the study by Jämsen (2013) a history of malignancy was associated with impaired survival of the hip prostheses (revision surgery) during ten years of follow-up in the univariate (HR: 1.28 (95%CI 1.06 to 1.55)) and multivariate (HR: 1.27 (95% CI 1.05 to 1.54)) adjusted model Jämsen, (2017).

Grading of evidence
Grading the evidence started at a level of low evidence, because the data used was derived from an observational study. Downgrading by one level was necessary, because of width of confidence interval (imprecision).

PICO 3: What are the favourable and unfavourable effects of total hip arthroplasty in patients with osteoarthritis and diabetes, versus patients with osteoarthritis and no diabetes?
No studies were found describing complications, functional gain and pain relief in patients with diabetes compared to patients without diabetes.

Survival
In the study by Jämsen (2013) diabetes did not affect survival of hip arthroplasties up to 5 years of follow-up in the univariate (HR: 1.08 (95%CI 0.88 to 1.34)) and multivariate (HR: 1.03 (95%CI 0.83 to 1.27)) adjusted model. Diabetes also did not affect survival of hip arthroplasties after five years of follow up in the univariate (HR: 0.77 (95%CI 0.29 to 2.06)) and multivariate (HR: 0.60 (95%CI 0.22 to 1.63)) adjusted model Jämsen, (2013).

Grading of evidence
Grading the evidence started at a level of low evidence, because the data used was derived from an observational study. Downgrading by one level was necessary because there was imprecision (width of confidence interval).

PICO 4: What are the favourable and unfavourable effects of total hip arthroplasty in obese patients with osteoarthritis, versus non-obese patients with osteoarthritis?
Complications
The study by Chee (2010) reported a significantly higher overall peri-operative complication rate in morbidly obese patients (12) compared to non-obese patients (3) (22% versus 5%, p = 0.012) Chee, (2010).

The study by Fu (2016) reported significant differences in any complication(s) overall, any major complication(s), wound complications, blood transfusions, return to the operating room and extended LOS between the different obesity classes (all P <0.004). All obesity classes were associated with having any complication (obese I OR 1.19, CI: 1.01 to 1.40 ; obese II OR 1.29, CI: 1.05 to 1.59; and obese III OR 1.54, CI: 1.21 to 1.98) and wound complications (obese I OR 1.80, CI: 1.30 to 2.50; obese II OR 2.18, CI: 1.47 to 3.25; and obese III OR 3.23, CI:

2.09 to 4.99). Obese II and obese III were also associated with return to operating room (obese II OR 1.59, CI: 1.16 to 2.18 and obese III OR 1.80, CI: 1.22 to 2.63). Obese III was the only obesity class that reached statistical significance as a predictor of extended LOS (OR 1.22, CI: 1.05 to 1.43) Fu, (2016).

The study by Davis (2011) reported a 6.8% risk of dislocation in patients with a BMI ≥35 kg/m^2 compared with a 3.2% risk of dislocation in patients with a BMI between 30 and 34.9, a 2.0% risk in patients with a BMI between 25 and 29.9 and a 1.5% risk in patients with a BMI lower than 25 kg/m^2. Multivariate adjustments showed a 113.9% increase in odds per 10 point BMI increase (CI: 11.5 to 308.1, p-value = 0.023). The risk of superficial infection was 14.2% in patients with a BMI of 35 kg/m^2 compared to 4.6% in patients with a BMI of 30 to 34.9, 3.7% in patients with a BMI between 25 and 29.9 and 4.4% in patients with a BMI lower than 25 kg/m^2. Multivariate analysis showed that there were no statistically significant differences between adjacent BMI groups, until the comparison between BMI ≥35 and 30 to 34.9, where patients in the heavier group had a 3.37 times (CI: 1.494 to 7.583) greater chance of superficial wound infection than those with a BMI between 30 and 34.9. Revision and deep infection were also not significantly different with a 10 point BMI increase Davis, (2011).

Grading of evidence
Grading the evidence started at a level of low evidence, because the data used was derived from observational studies. Downgrading by one level was, however, necessary as there were risk of bias (small sample size) and imprecision (width confidence interval).

Survival
The study by Chee (2010) reported a five-year survival, using revision surgery as an endpoint, of 90.9% (CI: 82.9 to 98.9) for morbidly obese patients and 100% for non-obese patients Chee, (2010).

Grading of evidence
Grading the evidence started at a level of low evidence, because the data used was derived from an observational study. Downgrading by one level was, however, necessary as there was imprecision (small sample size).

Functional gain
The study by Li (2017) reported that greater levels of obesity were associated with lower (worse) Physical Component Summary (PCS) scores 6 months after THR (trend test, p <0.001). However, the mean preoperative-to-postoperative changes in PCS scores did not significantly differ by BMI status (P=0.07). Differences in pre-operative-to-postoperative changes in the PCS score became greater after covariate adjustment, with severely and morbidly obese patients having substantially less gain than other patients (p <0.001) Li, (2017).

The study by Davis (2011) reported a 8.19% significant decrease in SF-36 score on physical function by 10 points BMI increase (CI: 4.74 to 11.63, p-value <0.001). This study also reported a 10.41 significant decrease in score for the category physical role limitation (CI: 4.64 to 16.18, p-value <0.001) Davis, (2011).

Grading of evidence

Grading the evidence started at a level of low evidence, because the data used was derived from an observational study. Downgrading by one level was necessary as there was a short follow-up time (risk of bias).

Pain relief
The study by Li (2017) reported that patients with greater levels of obesity had a greater improvement in the mean pre-operative-to-postoperative changes in Hip disability and Osteoarthritis Outcome Score (HOOS) (trend test, p <0.001). However, after covariate adjustment, pre-operative-to-postoperative pain relief did not significantly differ by BMI level Li, (2017).

The study by Davis (2011) reported a 3.98 significant decrease in SF-36 score on pain with every 10 points BMI increase (CI: 0.29 to 7.66, p-value <0.034) Davis, (2011).

Grading of evidence
Grading the evidence started at a level of low evidence, because the data used was derived from an observational study. Downgrading by one level was necessary as there were limitations in study design (short follow-up time) and imprecision (overlap confidence intervals).

PICO 5: What are the favourable and unfavourable effects of total hip arthroplasty in smokers with osteoarthritis, versus non-smokers with osteoarthritis?
No studies were found describing the outcomes in patients undergoing total hip arthroplasty who smoked compared to patients who did not smoke.

Zoeken en selecteren

To answer the question a systematic literature analysis was performed for the following research questions:

PICO 1: What are the favourable and unfavourable effects of total hip arthroplasty in patients with osteoarthritis using immunosuppressants, versus patients with osteoarthritis not using immunosuppressants?
P: patients with osteoarthritis of the hip who underwent total hip arthroplasty;
I: taking immunosuppressive medication;
C: not taking immunosuppressive medication;
O: complications, survival, functional gain, pain relief.

PICO 2: What are the favourable and unfavourable effects of total hip arthroplasty in patients with osteoarthritis and malignancy, versus patients with osteoarthritis and no malignancy?
P: patients with osteoarthritis of the hip who underwent total hip arthroplasty;
I: patients with malignancy;
C: patients without malignancy;
O: complications, survival, functional gain, pain relief.

PICO 3: What are the favourable and unfavourable effects of total hip arthroplasty in patients with osteoarthritis and diabetes, versus patients with osteoarthritis and no diabetes?
P: patients with osteoarthritis of the hip who underwent total hip arthroplasty;
I: patients with diabetes;

C: patients without diabetes;
O: complications, survival, functional gain, pain relief.

PICO 4: What are the favourable and unfavourable effects of total hip arthroplasty in obese patients with osteoarthritis, versus non-obese patients with osteoarthritis?
P: patients with osteoarthritis of the hip who underwent total hip arthroplasty;
I: patients with obesity;
C: patients without obesity;
O: complications, survival, functional gain, pain relief.

PICO 5: What are the favourable and unfavourable effects of total hip arthroplasty in smokers with osteoarthritis, versus non-smokers with osteoarthritis?
P: patients with osteoarthritis of the hip who underwent total hip arthroplasty;
I: patients who smoke;
C: patients who do not smoke;
O: complications, survival, functional gain, pain relief.

Relevant outcome measures
The working group did not define outcomes a priori, but used definitions as provided in the studies.

Search and select (Method)
A literature search was performed in the Medline database (via OVID) with relevant search terms on 18 September 2017. The search strategy is provided in the tab "Methods". The literature search resulted in 476 hits. Studies reporting complications, survival, functional gain and pain relief after THA in patients with osteoarthritis and obesity, malignancy, diabetes, patients using immunosuppressants or who smoke were selected. Initially, 16 studies were selected. After obtaining full text, 5 studies were included in the literature analysis.

The most important study characteristics are described in evidence-tables. The assessment of risk of bias is provided in risk of bias tables.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

Chee YH, Teoh KH, Sabnis BM, et al. Total hip replacement in morbidly obese patients with osteoarthritis: results of a prospectively matched study. J Bone Joint Surg Br. 2010;92(8):1066-71. doi: 10.1302/0301-620X.92B8.22764. PubMed PMID: 20675748.
Davis AM, Wood AM, Keenan ACM, et al. BallantyneDoes body mass index affect clinical outcome post-operatively and at

five years after primary unilateral total hip replacement performed for osteoarthritis? J Bone Joint Surg Br. 2011;93(9):1178-82. doi: 10.1302/0301-620X.93B9.26873.
Fu MC, D'Ambrosia C, McLawhorn AS, et al. Malnutrition Increases With Obesity and Is a Stronger Independent Risk Factor for Postoperative Complications: A Propensity-Adjusted Analysis of Total Hip Arthroplasty Patients. J Arthroplasty. 2016;31(11):2415-2421. doi:10.1016/j.arth.2016.04.032. Epub 2016 May 6. PubMed PMID: 27237966.
Jämsen E, Peltola M, Eskelinen A, et al. Comorbid diseases as predictors of survival of primary total hip and knee replacements: a nationwide register-based study of 96 754 operations on patients with primary osteoarthritis. Ann Rheum Dis. 2013;72(12):1975-82. doi: 10.1136/annrheumdis-2012-202064. Epub 2012 Dec 19. PubMed PMID: 23253916; PubMed Central PMCID: PMC3841739.
Li W, Ayers DC, Lewis CG, et al. Functional Gain and Pain Relief After Total Joint Replacement According to Obesity Status. J Bone Joint Surg Am. 2017;99(14):1183-1189. doi: 10.2106/JBJS.16.00960. PubMed. PMID: 28719557; PubMed Central PMCID: PMC5508191.

Patient Reported Outcome Measures (PROMs) bij een totale heup prothese (THP)

Uitgangsvraag

Welke Patient Reported Outcome Measures zijn geschikt om het effect van een totale heupvervanging te evalueren?

Aanbeveling

Registreer PROMs voorafgaand aan de plaatsing van een totale heupprothese en tijdens follow-up: in ieder geval bij indicatiestelling, en postoperatief na drie en twaalf maanden.

Gebruik de EQ-5D als algemene PROMs, en de NRS voor pijn in rust en bij activiteit.

Gebruik de HOOS-PS als gewrichtsspecifieke PROM (eventueel gecombineerd met de OHS om internationale vergelijking mogelijk te maken).

Overwegingen

In general there is an increased use of both disease-specific and general PROMs. PROMs might particularly be valuable for measuring the effect of specific (surgical) interventions or for evaluation of care. In the future, PROMs may possibly be useful for determining practice variation (NOV, 2012).

The Netherlands Orthopaedic Association (NOV) aims to identify a set of PROMs that can contribute to continuous improvement of orthopaedic care, through recording of the outcomes in quality registrations like the Landelijke Registratie Orthopedische Implantaten (LROI) (NOV, 2012).

The NOV recommends to use the EuroQol 5 dimensions (EQ-5D), a standardized instrument for measuring generic health status, as a general PROM. The NOV initially advised to measure pain (in rest and during physical activity) in patients undergoing total hip arthroplasty with the Visual Analogue Scale (VAS). However, the Numeric Rating Scale (NRS) seems at least equivalent to the VAS and is more feasible in clinical practice. As a joint-specific PROM for THA patients the NOV recommends the Hip disability and Osteoarthritis Outcome Score (HOOS PS: a questionnaire to measure the symptoms and limitations with THA patients), which might be combined with the Oxford Hip Score (OHS) to assess function and pain with THA patients. Combining the HOOS PS and OHS facilitates international comparisons (NOV, 2012).

The PROMs should be administered at the time of indication, and three months and one year after the operation (NOV, 2012).

Inleiding

This module is based on the advisory report of the Netherlands Orthopaedic Association: Patient Reported Outcome Measures. Advies Nederlandse Orthopaedische Vereniging 2012 (https://www.orthopeden.org/downloads/32/advies-proms-orthopedie.pdf).

Patient Reported Outcome Measures (PROMs) are questionnaires which patients complete. PROMs are intended to quantify burden of disease and therefore may be helpful in the measurement of quality of care. PROMs have been used for a long time in scientific studies, but their use in the evaluation of regular care is relatively new. It is important to define an optimal set of PROMs that can be used in the assessment of the effect of a total hip arthroplasty (THA) from a patients' perspective.

Samenvatting literatuur

The recommendations are based on the advisory report of the Netherlands Orthopaedic Association: Patient Reported Outcome Measures. Advies Nederlandse Orthopaedische Vereniging 2012 (https://www.orthopeden.org/downloads/32/advies-proms-orthopedie.pdf) (NOV, 2012).

Zoeken en selecteren

No systematic literature search was performed.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

NOV (2012). Patient Reported Outcome Measures. Advies Nederlandse Orthopaedische Vereniging (NOV) (https://www.orthopeden.org/downloads/32/advies-proms-orthopedie.pdf).

Operatietechnische aspecten bij een totale heup prothese (THP)

Deze module is onderverdeeld in vier submodules waarin de volgende uitgangsvragen worden behandeld:

1. Welk type lagering geniet de voorkeur bij totale heupprothese?
2. Wat is de optimale kopdiameter bij totale heupprothese?
3. Welk type prothese geniet de voorkeur?
4. Welke benadering geniet de voorkeur bij totale heupprothese: anterior, posterior of lateraal?

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Type lagering bij een totale heup prothese (THP)

Uitgangsvraag

Welk type lagering geniet de voorkeur bij totale heupprothese?

Aanbeveling

Gebruik bij voorkeur een metalen of keramische kop en een cross-linked polyethyleen kom.

Overwegingen

Considering the ever younger patient group being treated with THA, there is a growing need for more wear-resistant bearing materials that allows the use of larger femoral head components preventing dislocation, without increasing friction and allowing motion without component to component impingement.

During the last decade the tribological characteristics of bearing couples in hip arthroplasty have been improved resulting in less particle wear, diminished osteolysis and improved survivorship. On the one side the innovation in hard on hard bearings has led to better ceramics, using hot isostatic pressing with different and smaller grain sizes as well as higher grain density resulting in lower fracture risk. Modern ceramics show better wettability and lubrication and almost no wear, while furthermore these products are inert and locally not bioactive and therefore do not cause osteolysis. Additionally, improvements of designs have almost excluded rim impingement and chipping.

Polyethylene quality has been dramatically improved by cross-linking of the polyethylene chains. This can be performed by gamma irradiation creating free radicals that in turn are used for cross-linking. Free radicals however are also responsible for oxidative degradation of polyethylene. This can either be prevented through vitamin E stabilisation, or through heating of the polyethylene, in that way capturing remaining free radicals. Heating is performed by remelting or annealing (below melting temperature of the polyethylene), which have both advantages and disadvantages in terms of changing polyethylene crystallinity and wear properties.

Most information concerning the tribological properties of these materials has come from in-vitro preclinical testing using hip simulators. Furthermore, the clinical assessment of linear and volumetric wear has been improved by using radiostereometry. However long-term data on survivorship using different combinations of bearing materials have been lacking and only gradually become available.

Summarising the available evidence, it can be said that metal-on-conventional-polyethylene carries a higher risk of revision than all other couplings (metal–on-cross linked-polyethylene, ceramic-on-conventional-polyethylene, ceramic-on-cross-linked-polyethylene, ceramic-on-ceramic). Because ceramic-on-ceramic shows lowest volumetric wear, it allows the use of large femoral heads diminishing the risk of dislocation in the young and active age group. In some studies however, survivorship of this coupling seems to be compromised through ceramic fractures and chipping of the older designs. Because of the more wear-resistant properties of cross-linked polyethylene (compared to conventional polyethylene), thinner cross-linked polyethylene is possible, also allowing larger femoral head components. Consequently, the use of these improved polyethylenes has a similar advantage as ceramic liners in terms of reducing dislocation risk. In some cases of ceramic-on-ceramic

couplings, patients may complain of squeaking. Although there is no evidence of any relation with wear or higher fracture risk, this may be a cause for revision because of the annoying sound. The combination of ceramic or metal on cross-linked polyethylene seems to be the most safe, durable and cost-effective, although there is no clear evidence of its superiority over ceramic-on-conventional polyethylene in long-term follow-up studies of good quality. In certain circumstances (younger non-obese patients, head size ≥32mm) ceramic-on-ceramic might also be a good choice.

Inleiding

Only a few materials are suitable as joint bearings for a total hip prosthesis. Traditionally the bearing materials consist of a metal femoral head and a polyethylene cup. Some disadvantages of these materials include wear, with osteolysis and implant loosening, and - dependent on head size - dislocation. To diminish these risks, alternative materials have been developed, creating less wear and at the same time providing the opportunity of using larger heads to decrease the risk of dislocation. Although the more wear-resistant properties of these materials have been illustrated in hip simulators and short-term to mid-term clinical follow-up, it is still unknown whether improved tribological properties will result in reduced wear and osteolysis and consequently in improved implant survival, in the mid to long term. Currently, a number of total hip bearing materials are available, which are used in the following combinations (see Table 1).

Table 1

Head	Cup
Metal	Conventional polyethylene
Metal	Cross-linked polyethylene
Metal	Metal
Ceramic	Conventional polyethylene
Ceramic	Cross-linked polyethylene
Ceramic	Ceramic

The working group chose to focus this chapter on three relatively new bearing materials (compared to traditional materials):

1. Cross-linked polyethylene cup (compared to conventional polyethylene cup).
2. Ceramic head (compared to metal head).
3. Ceramic insert (compared to conventional or cross-linked polyethylene insert) in uncemented cup.

There is strong advice against the use of large-head metal on metal articulations in the Netherlands (NOV, 2015) and the disappointing outcomes of these large-head metal on metal articulations reported in the European and Australian registries confirm the problems associated with these articulations. There are many unexpected findings in the metal on metal articulations leading to toxic metal ion loads in patients causing general medical problems and local hip joint problems, such as pseudotumours and loosening. Therefore, studies using metal on metal articulations are not included in this analysis.

Conclusies

PICO 1

Revision

Very low GRADE	Highly-cross-linked-polyethylene cups might be associated with a lower revision risk than conventional polyethylene cups. *Sources (Yin, 2015; Paxton, 2014; Paxton, 2015; Epinette, 2016; AOANJRR, 2016)*

Wear

High GRADE	Wear is reduced for highly-cross-linked polyethylene cups as compared to conventional polyethylene cups. *Sources (Shen, 2014; Langlois, 2015; Glyn-Jones, 2015)*

Osteolysis

High GRADE	No differences in osteolysis were found after 5 to 10 years follow-up for highly cross-linked cups compared to conventional polyethylene cups. *Sources Shen, (2014)*

PICO 2

Revision

Low GRADE	There seems to be no difference in risk of revision between ceramic heads and metal heads (both on (highly-cross-linked) polyethylene cups). *Sources Yin, (2015)*

PICO 3

Revision

Low GRADE	Ceramic-on-ceramic versus ceramic-on-highly-cross-linked-polyethylene showed similar revision risks. *Sources (Yin, 2015; Dong, 2015; Hu, 2015; Si, 2015, Beaupré, 2016)*

Ceramic fractures

Moderate GRADE	Ceramic-on-ceramic showed a 4 to 6 times higher rate of ceramic fractures than ceramic-on-polyethylene. *Sources (Dong, 2015; Hu, 2015; Si, 2015)*

Dislocation

Low GRADE	The incidence of dislocation seems to be comparable for ceramic-on-ceramic and ceramic-on-highly-cross-linked-polyethylene. *Sources (Dong, 2015; Hu, 2015; Si, 2015; Beaupré, 2016)*

Wear

Moderate GRADE	Wear is reduced for ceramic-on-ceramic as compared to ceramic-on-(highly-cross-linked)-polyethylene. *Sources Dong, (2015)*

Osteolysis

Moderate GRADE	No differences in osteolysis were found for ceramic-on-ceramic as compared to ceramic-on-highly-cross-linked-polyethylene. *Sources (Dong, 2015; Hu 2015)*

Samenvatting literatuur

Description of studies

Systematic reviews

A network meta-analysis was included that analysed the difference in the risk of revision or prosthesis survival using 40 RCTs involving 5321 total hip arthroplasties (THAs), with a postoperative follow-up of at least two years, for different bearing material combinations Yin, (2015). This study systematically reviewed and meta-analysed RCTs among commonly used THA bearing surfaces, including ceramic-on-ceramic, ceramic-on-conventional polyethylene, ceramic-on-highly-cross-linked polyethylene, metal-on-conventional polyethylene, metal-on-highly-cross-linked polyethylene and metal-on-metal articulations Yin, (2015).

Furthermore, four systematic reviews were found that compared two combinations of bearing materials each time, partly these included the same RCTs as Yin (2015).

Dong (2015) compared ceramic-on-ceramic and ceramic-on-polyethylene (highly cross-linked polyethylene, polyethylene, uncrosslinked ultrahigh molecular weight polyethylene and ultrahigh molecular weight polyethylene liner) total hip prostheses including eight RCTs enrolling a total of 1,508 patients and 1,702 THA surgeries. Follow-up of the included studies varied from 2 to 12 years. Outcomes reported were clinical outcomes, complications such as fractures, dislocation, osteolysis and revision rates, and radiographic outcomes Dong, (2015).

Hu (2015) compared ceramic-on-ceramic versus ceramic-on-polyethylene (highly cross-linked polyethylene, uncrosslinked ultrahigh molecular weight polyethylene) bearing surfaces for THA in 9 RCTs involving 1575 patients (1747 hips). Follow-up varied from 12 to 96 months postoperatively. Outcomes reported were ceramic fractures, dislocation, revision and osteolysis Hu, (2015).

Shen (2014) compared highly cross-linked polyethylene with conventional polyethylene bearing surfaces for THA in 8 RCTs involving 735 patients. Follow-up ranged from 5 to 10 years. Outcomes reported were wear-related revision and osteolysis Shen, (2014).

Si (2015) compared ceramic-on-ceramic with ceramic-on-polyethylene (highly cross-linked polyethylene, moderately cross-linked polyethylene, uncross-linked ultra-high-molecular-weight polyethylene) bearing surfaces for THA in 13 RCTs involving 2488 THAs. Follow-up ranged from one to twelve years. Outcomes reported were revision and overall ceramic fractures Si, (2015).

RCTs

In addition, three RCTs were found that were not included in the network meta-analysis of Yin (2015).

Beaupré (2016) compared ceramic-on-ceramic with ceramic-on-highly-cross-linked-polyethylene in an RCT in 92 subjects. Ten-year follow-up was completed in 35 of the 48 patients in the ceramic-on-ceramic group and in 33 of the 44 patients in the ceramic-on-highly-crosslinked-polyethylene group. Outcomes reported were PROMs, wear and revision Beaupré, (2016).

Glyn-Jones (2015) performed an RCT that compared long-term steady wear of highly-cross-linked-polyethylene with ultra-high-molecular-weight-polyethylene. Outcomes reported were revision and wear Glyn-Jones, (2015).

Langlois (2015) conducted a prospective randomised study to assess the rates of penetration in 100 patients of two distinct types of polyethylene in otherwise identical cemented all-polyethylene acetabular components. After 8 years of follow-up 68 hips had complete follow-up data Langlois, (2015).

Registry studies

Several registry studies were found. Paxton (2014) compared risk of revision between metal-on-conventional-polyethylene and metal-on-highly-cross-linked-polyethylene in six national and regional registries: USA (Kaiser Permanente, HealthEast), Italy (Emilia-Romagna region), Spain (Catalan region), Norway and Australia. Inclusion criteria were osteoarthritis as the primary diagnosis, cementless implant fixation and a patient age of 45 to 64 years. These criteria resulted in a sample of 16,571 primary THAs Paxton, (2014).

Paxton (2015) describes 26,823 THAsfrom the Kaiser Permanente's Total Joint Replacement Registry performed between April 2001 and December 2011. Endpoints of interest were all-cause and aseptic revisions. Of the 26,823 THAs included in the study, 1815 (7%) were metal-on-conventional polyethylene and 25,008 (93%) were metal-on-highly-cross-linked-polyethylene Paxton, (2015).

Epinette (2016) analysed data from the National Joint Registry (England and Wales) of 45,877 hips. It compared cross-linked annealed polyethylene (n=21,470) with conventional polyethylene (n=8,225) and ceramic-on-ceramic (n=16,182) at six years follow-up and focused on revision risk Epinette, (2016).

Furhermore, the 2016 Annual Report of the Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) was used (AOANJRR, 2016).

Results

PICO 1: What are the effects of a cross-linked polyethylene cup, compared to a conventional polyethylene cup, on ceramic fractures, dislocation, wear, revision, survival and osteolysis in primary total hip arthroplasty for osteoarthritis or avascular necrosis?

Revision

The network meta-analysis of 40 RCTs showed no significant difference in relative risk (RR) of revision for metal-on-highly-cross-linked-polyethylene versus metal-on-conventional-polyethylene (11 studies, RR for conventional polyethylene vs highly-cross-linked-polyethylene = 2.04 (0.89 to 5.09) Yin, (2015).

The study by Paxton (2014) showed a five-year rate of revision surgery ranging from 1.9% to 3.2% among the different registries. There was no significant difference in revision rates between bearing surfaces, with a hazard ratio of 1.20 (95% CI 0.80 to 1.79) for metal-on conventional-polyethylene compared to metal-on-highly-crosslinked-polyethylene Paxton, (2014).

The large registry study by Paxton (2015) included 26,823 patients with a follow-up up to 10 years (median follow-up 5.1 years). The adjusted risks of all-cause revision (HR 1.75; 95%CI, 1.37 to 2.24; p<0.001) and aseptic revision (HR 1.91; 95% CI, 1.46 to 2.50; p<0.001) were higher in patients with metal-on-conventional-polyethylene bearing surfaces compared with metal-on-highly-cross-linked-polyethylene. At 7 years follow-up, the cumulative incidence of revision was 5.4% (95% CI, 4.4% to 6.7%) for metal-on-conventional-polyethylene and 2.8% (95% CI, 2.6% to 3.2%) for metal-on-highly-cross-linked-polyethylene. When accounting for differences in femoral head size distribution, the results were not substantively different Paxton, (2015).

The National Joint Registry of England and Wales hip data set, including 45,877 hips, showed better survival (revision for any cause) for cross-linked annealed polyethylene (6 years survival rate 98.0%; 95%CI 0.976-0.983) versus conventional polyethylene (6 years survival rate 97.3%; 95%CI 0.969-0.977; p=0.072) Epinette, (2016). When considering revision for bearing related failures, 6-year survival was significantly better for cross-linked annealed polyethylene (99.6%) than for conventional polyethylene (98.8%; P<0.001). Separate analyses were carried out for small metallic heads, small alumina heads and large heads. For metallic and alumina small heads (≤32mm), survival of cross-linked annealed polyethylene was significantly better than of conventional polyethylene. For large heads this comparison could not be made because there were no large heads used in combination with conventional polyethylene liners Epinette, (2016).

According to the 2016 Annual Report of the Australian Orthopedic Association National Joint Replacement Registry (AOANJRR), which contains 363,561 primary THAs, of which 44,710 hips were added in 2015, cross-linked-polyethylene has a lower rate of revision than conventional polyethylene regardless of the femoral head used (both independent of size and bearing material); the 15-year cumulative percent revision for cross-linked-polyethylene is 5.6% versus 10.5% for non-cross-linked-polyethylene (AOANJRR, 2016). The cumulative incidence of loosening/lysis and prosthesis dislocation at 15 years is 1.1% and 1.2% for cross-linked-polyethylene, compared to 3.6% and 1.6% for non-cross-linked-polyethylene bearings respectively (AOANJRR, 2016).

Revision varies depending on head size. In the Australian registry, this is most evident for non-cross-linked-polyethylene where the rate of revision increases with larger head size, mainly due to osteolysis and loosening (AOANJRR, 2016). For cross-linked-polyethylene there is no difference between head sizes <32 mm and >32 mm, but revision risk is lowest for 32 mm heads (AOANJRR, 2016).
Comparing all bearing combinations, the cumulative percent revision at 10 years for ceramic-on-cross-linked-polyethylene and metal-on-cross-linked-polyethylene is lower (respectievelijk 4.4; 4.0 to 4.8 and 4.3; 4.1 to 4.5), compared to ceramic-on-non-cross-linked-polyethylene and metal-on-non-cross-linked-polyethylene (7.0; 6.3 to 7.8 and 6.3; 6.1 to 6.6). The percent revision of ceramic-on-ceramic lies in between the cross-linked-polyethylene and non-cross-linked-polyethylene values (5.0; 4.8 to 5.3) (AOANJRR, 2016).

Fractures

Highly-cross-linked-polyethylene versus conventional polyethylene

None of the studies reported fractures.

Dislocation

Highly-cross-linked-polyethylene versus conventional polyethylene

None of the studies reported dislocation.

Wear

Highly-cross-linked-polyethylene versus conventional polyethylene

A meta-analysis of 8 RCTs that compared highly-cross-linked with conventional polyethylene showed significantly reduced radiological wear (weighted mean difference = -0.09; 95% CI - -0.15 to -0.03; p=0.006) of cross-linked polyethylene, but no difference in wear-related revision (RD = -0,02, 95% CI =-0.05 to 0.01, P=0.20) after five to ten years follow-up Shen, (2014). However, the study did not provide information on the bearing material at the femoral side Shen,(2014).

Two small RCTs were published after this review.

Langlois (2015) showed that at nine year follow-up the yearly linear wear can be significantly reduced by using a highly cross-linked PE (-0.0002 mm/year versus 0.132 mm/year for contemporary annealed polyethylene, p<0.001) Langlois, (2015).

Glyn-Jones (2015) reported linear wear (using radiostereometric analysis) for the highly cross-linked polyethylene being significantly less (0.003 mm/year) than for the conventional ultrahigh-molecular weight polyethylene (0.030 mm/year; p<0.001) at 10 years. The volumetric wear between 1 and 10 years was lower in the highly-cross-linked-polyethylene group (14 mm3) compared to the conventional ultrahigh-molecular weight polyethylene group (98 mm3, p = 0.01) Glyn-Jones, (2015).

Osteolysis

Highly-cross-linked-polyethylene versus conventional polyethylene

A meta-analysis of 8 RCTs that compared highly cross-linked with conventional polyethylene showed no difference in osteolysis (RD = -0.12, 95% CI =-0.26 to 0.03, P=0.12) after five to ten years follow-up Shen, (2014).

Grading of evidence

Revision

Level of evidence started as low as the conclusion was based on the network meta-analysis of Yin (2015) together with observational registry data, and was downgraded to very low because of heterogeneity in the results.

Wear

The level of evidence was graded as high since the conclusion for wear was based on the systematic review of Shen (2014), which was of good quality, together with two RCTs.

Osteolysis

The level of evidence was graded as high as the systematic review of Shen (2014) was of good quality.

PICO 2: What are the effects of a ceramic head, compared to a metal head, on fractures, dislocation, wear, revision, survival and osteolysis in primary total hip arthroplasty for osteoarthritis or avascular necrosis (*with use of the same type of polyethylene on the cup side)*?

Revision

The network meta-analysis of 40 RCTs showed no significant difference in risk of revision for ceramic-on-conventional-polyethylene prosthesis versus metal-on-conventional-polyethylene (3 studies; RR 1.74 (0.58 to 5.24) Yin, (2015). There was also no significant difference in risk of revision for ceramic-on-highly-cross-linked-polyethylene versus metal-on-highly-cross-linked polyethylene (2 studies; RR 0.74; 95% CI 0.17; 3.01) Yin, (2015).

Ceramic fractures

None of the studies reported ceramic fractures.

Dislocation

None of the studies reported dislocation.

Wear

None of the studies reported wear.

Osteolysis

None of the studies reported osteolysis.

Grading of evidence

Revision

The conclusion is based on the meta-analysis of RCT's by Yin (2015), therefore the level of evidence started as high. The level of evidence was downgraded one level for risk of bias (in most included studies details regarding randomisation and blinding were not clear) and one level for heterogeneity of the results. Level of evidence was graded as low.

PICO 3: What are the effects of a ceramic insert (in uncemented cup), compared to a (conventional or cross-linked) polyethylene insert (in uncemented cup), on fractures, dislocation, wear revision, survival and osteolysis in primary total hip arthroplasty for osteoarthritis or avascular necrosis?

Revision
A network meta-analysis of 40 RCTs showed that the relative risk of revision for ceramic-on-highly-cross-linked polyethylene versus ceramic-on-ceramic was 1.95 (4 studies; 95% CI 0.68-6.60) Yin, (2015).

A meta-analysis of 8 RCTs that compared ceramic-on-ceramic versus ceramic-on-(highly cross-linked)-polyethylene showed no difference in revision rate (RR=0.99; 95% CI (0.54 to 1.83)) Dong, (2015).

Another meta-analysis of 9 RCTs that made the same comparison, did not show differences in revision rates for ceramic-on ceramic compared to ceramic-on-polyethylene (2.7% versus 2.8%) Hu, (2015).

A third meta-analysis of 13 RCTs showed no differences with respect to revisions (RR 1.28 (0.60 to 2.75)) Si, (2015).

The RCT by Beaupré (2016) reported three revisions in the ceramic-on-highly-crosslinked-polyethylene group and no revisions in the ceramic-on-ceramic group. The results might be caused by the differences in head sizes (mainly 28 mm ceramic-on-highly-crosslinked-polyethylene vs 32 mm in ceramic-on-ceramic) Beaupré, (2016).

Ceramic fractures
A meta-analysis of 8 RCTs that compared ceramic-on-ceramic versus ceramic-on-(highly cross-linked)-polyethylene showed a higher rate of fractures (5 studies) for ceramic-on-ceramic fracture than ceramic-on-(highly-cross-linked) polyethylene (RR = 4.46, 95% CI: 1.16 to 17.25; P = 0.03) Dong, (2015).

Another meta-analysis of 9 RCTs also showed a higher incidence of intra- and postoperative fractures (6 studies) for ceramic-on-ceramic than ceramic-on-polyethylene (Risk ratio 5.10 (1.32 to 19.71); P=0.02) Hu, (2015).

A third meta-analysis of 13 RCTs also showed a higher rate of overall fractures (6 studies) for ceramic-on-ceramic than ceramic-on-polyethylene (RR 6.02 (95%CI (1.77 to 20.1)) Si, (2015).

Dislocation
A meta-analysis of 8 RCTs that compared ceramic-on-ceramic versus ceramic-on-(highly-cross-linked) polyethylene showed no significant difference in dislocation rate (RR=0.73 (95%CI 0.44 to 1.19). There was no information on head sizes used in the studies Dong, (2015).

Another meta-analysis of 9 RCTs Hu, (2015) made the same comparison and found no significant difference in dislocation rates between ceramic-on-ceramic versus ceramic-on-polyethylene (3.1% versus 4%, RR = 0.77 (0.47 to 1.25); P=0.29).

A third meta-analysis of 13 RCTs showed no differences with respect to dislocations (RR 0.72 (95%CI (0.43 to 1.19)) Si, (2015).

The RCT by Beaupré (2016) reports four patients with recurrent dislocations in the ceramic-on-highly-crosslinked-polyethylene group (of which three underwent a surgical revision), and two in the ceramic-on-ceramic group.

Wear
Three studies in the meta-analysis by Dong (2015) that compared ceramic-on-ceramic versus ceramic-on-(highly-cross-linked) polyethylene reported wear rate. In the ceramic-on-ceramic group, the mean linear wear rate was 30.5 ± 7.0 µm/year and the mean volumetric wear rate was 21.5 ± 4.5 mm3/year. In the ceramic-on-polyethylene group, the mean linear wear rate was 218.2 ± 13.7 µm/year and the mean volumetric wear rate was 136.2 ± 8.5 mm3/year. The increase in mean linear and volumetric wear rates in the ceramic-on-polyethylene group was statistically significant (P <0.001) Dong, (2015).

Osteolysis
Dong (2015) showed no significant difference in osteolysis rate in a meta-analysis (four studies reported osteolysis) between the ceramic-on-polyethylene and the ceramic-on-ceramic group (RR = 0.39 (in favour of COC), 95% CI: 0.10 to 1.56, P = 0.18).

A pooled analysis of 7 studies (1155 hips) revealed no significant difference in the incidence of osteolysis and radiolucent lines in the ceramic-on-ceramic and ceramic-on-polyethylene groups (0.3% versus 1.2%, respectively; RR=0.43; 95% CI, 0.11-1.68; P=.22; homogeneity, P=.80) Hu, (2015).

Grading of evidence
Revision
Level of evidence was graded as low as the systematic literature search by Dong (2015) and Hu (2015) was not completely clear and results were heterogeneous.

Fractures
The level of evidence was graded as moderate as the systematic literature search by Dong (2015) and Hu (2015) was not completely clear and adjustment for potential confounders was unclear in Dong (2015) and Si (2015). Due to these methodological limitations it was graded as moderate.

Dislocation
The level of evidence was downgraded by two levels to low. One level because the systematic literature search by Dong (2015) and Hu (2015) was not completely clear and adjustment for potential confounders was unclear in Dong (2015) and Si (2015). In addition, the level was downgraded by one level because results were heterogeneous.

Wear
The level of evidence was graded as moderate as the systematic literature search by Dong (2015) was not completely clear.

Osteolysis
The level of evidence was graded as moderate as the systematic literature search by Dong (2015) was not completely clear.

Zoeken en selecteren

To answer the question, a systematic literature analysis was performed for the following research questions:

PICO 1: What are the effects of a cross-linked polyetheylene cup, compared to a conventional polyethylene cup, in primary total hip arthroplasty for osteoarthritis or avascular necrosis?
P: primary total hip arthroplasty for osteoarthritis or avascular necrosis;
I: cross-linked polyethylene cup;
C: conventional polyethylene cup;
O: periprosthetic fractures, dislocation, wear, revision, survival, osteolysis.

PICO 2: What are the effects of a ceramic head, compared to a metal head, in primary total hip arthroplasty for osteoarthritis or avascular necrosis (with use of the same type of polyethylene on the cup side)?
P: primary total hip arthroplasty for osteoarthritis or avascular necrosis;
I: ceramic head;
C: metal head;
O: periprosthetic fractures, ceramic fractures, dislocation, wear, revision, survival, osteolysis.

PICO 3: What are the effects of a ceramic insert (in uncemented cup), compared to a cross-linked polyethylene insert (in uncemented cup), in primary total hip arthroplasty for osteoarthritis or avascular necrosis?
P: primary total hip arthroplasty for osteoarthritis or avascular necrosis;
I: ceramic insert (in uncemented cup);
C: conventional or cross-linked polyethylene insert (in uncemented cup);
O: periprosthetic fractures, ceramic fractures, dislocation, wear, revision, survival, osteolysis.

Relevant outcome measures
De working group decided that revision (for any reason) and survival were critical outcome measures for decision-making; and osteolysis and wear were important for decision-making.

The working group defined these outcomes in the following way:

- Revision was defined as the exchange of any component of the femoral implant (stem and/or head) or the acetabular implant (cemented cup or uncemented cup and/or insert), for aseptic loosening and/or any other reason.
- Survival was defined as the revision-free presence of the implant component(s) in the human body during clinical follow-up.
- Wear is the tribological phenomenon of volumetric loss of material due to friction of contacting surfaces in relative motion. Amongst others, this can be assessed with conventional radiography or radiostereometry. Dependent on the type of wear (abrasive, adhesive, fatigue, delamination or third body), the type of

material (metal, ceramic, polyethylene, other materials) and the size and dose of the wear-particles, this can result in osteolysis and eventually loosening of the implant.

Search and select (Method)
A literature search was performed with relevant search terms on 17 november 2016 in the databases Medline (OVID) and Embase (via Embase.com). The search strategy is provided in the tab "Methods". The literature search resulted in 1558 hits. Studies were selected using the following selection criteria: systematic reviews of RCTs or RCTs, comparing the material combinations in the research questions identified, follow-up of preferably five to ten years or more. After obtaining full text, relevant and high quality studies were included in the literature analysis. Based on title and abstract 43 studies were pre-selected. After reading full text, 36 studies were excluded (see exclusion table below) and 7 studies were selected. In addition, four national hip registry studies were included.

The most important study characteristics are described in evidence tables. The assessment of risk of bias is provided in risk of bias tables.

Verantwoording

Laatst beoordeeld : 12-02-2019
Laatst geautoriseerd : 12-02-2019

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

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Kopdiameter bij een totale heup prothese (THP)

Uitgangsvraag

Wat is de optimale kopdiameter bij totale heupprothese?

Aanbeveling

Gebruik bij voorkeur een 32 mm kop bij totale heupartroplastiek.

Overwegingen

In the past, most total hip implants had a femoral head diameter of 22, 28 or 32mm. To overcome one of the major complications after a total hip arthroplasty - dislocation - there has been a trend to larger heads of 36mm and more. However, this trend is not without disadvantages. Larger heads lead to more friction and more wear. In addition, especially in these larger head sizes the choice of the bearings seems to be more critical.

There is a strong trend in many registries to use 32mm heads. This trend is relatively safe, the dislocation tendency of a 32mm head is lower than a 22 or 28mm head and there is no evidence that it will result in higher overall revision rates. However, in some studies using heads larger than 32mm to prevent dislocation, less favourable results have been reported.

It is rather complicated to draw clear scientific conclusions as other factors also play a role, like patient selection, type of bearing and surgical approach. In addition, as already stated the rate of dislocations who have been treated conservatively are greatly underestimated in many studies due to the study design.

It is advisable to use 32mm heads in most patients. Smaller heads still may be indicated in cases with abnormal anatomy. If a larger head diameter than 32mm is indicated, it seems best to use a ceramic-on-ceramic prosthesis, although there is little scientific evidence to support that.

Dual mobility cups
In the last decade there is a new trend to use dual mobility cups in primary THA to prevent dislocation, especially in patients with a higher risk of dislocation. These implants do not fit within the definitions used in this chapter to study the effect of head size on dislocation. However, since this type of implant is being used in the same patients, it is important to pay attention to these devices in this considerations paragraph.

In a literature analysis performed on 6 january 2018 four studies of interest were found. The largest study by Darrith (2018) was based on a literature review of 54 papers and the authors included 10,783 THAs who had a dual mobility cup, with a mean follow-up of 8.5 years (range 2 to 16.5). The mean rate of extra-articular dislocation was 0.46% (41 hips), which is lower than after routine single bearing THA. The overall rate of revision (any revision of the acetabular component or the dual mobility bearing) was 2.0% (178 hips). However, in the 2016 Report of the Australian Registry, dual mobility prostheses have a higher rate of revision compared to other acetabular prostheses at 5 years or more.

Dual mobility articulations are a viable alternative to traditional bearing surfaces in cases with a high risk for

dislocation, however high-quality studies are needed to evaluate further the use of dual mobility components in THA.

Inleiding

Since the last version of the Dutch guidance on primary total hip arthroplasty (THA), more data have become available, especially from the registries, on the trends in head sizes used worldwide and there is more evidence about the most effective head size. However, head size cannot be seen independently from the coupling bearing used.

The most frequently used head sizes of hip prostheses are 28 and 32 mm. Larger and smaller head sizes are also used and especially in the last decade there is a trend towards the use of bigger heads. The hypothesis is that larger head sizes are associated with lower dislocation rates. We are especially interested in the effect of head size on the frequency of dislocation, on complications, on the risk of revision for instability and on the overall risk of revision.

To include the relatively new trend of using dual mobility cups in primary THA to prevent dislocation, we have added a short comment on the growing use of these newer designs in the considerations section.

Conclusies

Risk of revision

Very low GRADE	It is unclear whether head size has an effect on revision rate for hip prostheses consisting of a metal head on a highly-cross-linked-polyethylene liner. Based on registry data in most cases a 32mm head on a highly-cross-linked-polyethylene liner tends to be the safest option. *Sources (Allepuz, 2014;* AOANJRR, 2016; *NJR, 2016)*

Very low GRADE	There seems to be a lower risk of revision when a larger head was used using ceramic-on-ceramic implant. *Sources (Sedrakyan, 2014;* AOANJRR, 2016; *NJR, 2016)*

Samenvatting literatuur

Description of studies
Two large studies based on registries were included in the literature analysis (Allepuz, 2014; Sedrakyan, 2014). They both described data from the same six national and regional registries: Kaiser Permanente, HealthEast, the Emilia-Romagna region in Italy, the Catalan region in Spain, Norway, and Australia. However, the reviews focus on outcome of head size with different bearing types.

Allepuz (2014) studied the effect of femoral head size on the risk of revision when an HXLPE liner was used on a metal head. In this study, 14,372 THAs were included. Main outcome was risk of revision (for any reason). A possible bias of this study was that the included group of patients was limited in age (only patients between the age of 45 to 65 were included) Allepuz, (2014).

Sedrakyan (2014) compared femoral head sizes of >28mm and ≤28 mm for ceramic-on-ceramic articulations and compared ceramic-on-ceramic with metal-on-HXLPE articulations. A total of 34,985 patients were included. Main reported outcome was risk of revision (for any reason) Sedrakyan, (2014).

In addition, annual registry reports from Australia and the UK of 2016 were analysed and included, as both reports focussed on the influence of head size on the outcomes, with endpoints revision for dislocation or revision for any reason (AOANJRR, 2016; NJR, 2016).

Results

Revision

In the study by Allepuz (2014), for highly-cross-linked-polyethylene liner on metal head implants, the risk of revision (for any reason) did not differ significantly between <32mm and 32-mm head sizes (hazard ratio (HR) = 0.91, 95% confidence interval (CI) = 0.69 to 1.19) or between >32-mm and 32-mm sizes (HR = 1.05, 95% CI = 0.70 to 1.55) Allepuz,(2014).

Sedrakyan (2014) found a lower risk of revision associated with use of ceramic-on-ceramic implants when a larger head size (>28mm) was used, compared to ≤28mm (HR (hazard ratio) = 0.73, 95% CI (confidence interval) = 0.60 to 0.88, p = 0.001). Use of ≤28mm head in ceramic-on-ceramic bearings was associated with a higher risk of failure compared with any head size metal-on- highly-cross-linked-polyethylene bearings (HR = 1.36, 95% CI = 1.09 to 1.68, p = 0.006). Use of >28mm head ceramic-on-ceramic bearings was associated with a small protective effect relative to any head size metal-on- highly-cross-linked-polyethylene bearings (not subdivided by head size) in years zero to two, but this difference dissipated over the longer term Sedrakyan, (2014).

The Australian registry report 2016 (AOANJRR, 2016) showed that risk of revision for any reason varied depending on head size. This was most evident for non-cross-linked-polyethylene (table HT29), where the rate of revision after five years was 8.7% (95% CI 5.6 to 13.2) for >32mm, compared to 3.7% (95% CI 3.2 to 3.6) for 32 mm, and 3.4% (95% CI 3.2 to 3.6) for <32mm. However, the number of patients in the >32mm group was small. After ten years, the rate of revision was 5.9% (95% CI 5.0 to 6.9) for 32 mm and 6.5% (95% CI 6.2 to 6.8) for <32mm heads (no data for >32mm) (AOANJRR, 2016).

For highly cross-linked-polyethylene, 32mm head size had the lowest rate of revision relative to both smaller and larger heads. There was no difference between head sizes smaller than 32mm and bigger than 32mm. The rate of revision after five years was 3.1% (95% CI 2.9 to 3.2) for >32mm, compared to 2.6% (95% CI 2.5 to 2.7) for 32 mm, and 2.9% (95% CI 2.8 to 3.1) for <32mm. After ten years, the rate of revision was 4.4% (95% CI 4.0 to 4.8) for >32mm head, 3.8% (95% CI 3.6 to 4.1) for 32 mm and 4.4% (95% CI 4.1 to 4.6%) for <32mm heads (AOANJRR, 2016).

For ceramic-on-ceramic articulations (AOANJRR, 2016; table HT31), head size ≥32mm had a lower rate of revision compared to head sizes 28mm or less. There was no difference when head size 32 mm was compared to the 36-38mm head size group. Head sizes 40 mm or larger had a lower rate of revision compared to the other sizes, although marginally significant and depending on fixation type. After five years, the rate of revision for ≤28mm was 4.3% (95% CI 3.8 to 4.8), for 32mm 3.1% (95% CI 2.9 to 3.3), for 36 to 38mm 3.1% (95% CI 2.9 to 3.3), and for ≥40mm 2.4% (95% CI 2.0 to 3.0). After ten years, the rate of revision for ≤28mm was 6.6% (95% CI 6.0 to 7.3), for 32mm 4.8% (95% CI 4.4 to 5.1) and for 36-38mm 5.0% (95% CI 4.5 to 5.5). There were no data for ≥40mm after ten years (AOANJRR, 2016).

The UK report 2016 of the National Joint Registry (NJR, 2016) showed that for metal-on- polyethylene (unspecified) cemented monobloc cups, there was a statistically significant effect of head size (overall difference P<0.001 by logrank test) on revision rates (NJR, 2016). Up to five years, implants with a head diameter of 36mm had the worst failure rates compared to all smaller heads. At ten years, implants with a head diameter of 32mm were worse than those with head sizes of 22-25mm, 26mm and 28mm (NJR, 2016).

Revision rates for different head sizes for metal-on-polyethylene uncemented metal shell with polyethylene liners were also analysed. There was a statistically significant effect of head size (overall P<0.001), with head size 44mm showing worse failure rates, but there were small numbers after five years (NJR, 2016)

For ceramic-on-polyethylene cemented monobloc cups there was a statistically significant difference between the head sizes overall (P=0.002) and the largest head size 36mm showing worse failure rates (NJR, 2016).

For ceramic-on-polyethylene uncemented metal shells used with polyethylene liners, there was a statistically significant difference between the three head sizes (P=0.005), the best survival rate was in the intermediate size group (32mm) with 28mm and 36mm both showing similar worse outcomes (NJR, 2016).

For ceramic-on-ceramic uncemented metal shells used with ceramic liners head sizes 28mm, 32mm, and 36mm showed similar worse failure rates (P=0.01). Head size 40mm showed the best survival rate, though there were small numbers available (NJR, 2016).

Grading of evidence
Risk of revision
Risk of revision was reported in several registries, which are observational studies that are graded as low level of evidence. Results for highly cross-linked polyethylene were inconsistent. Moreover, the number of included patients with a ceramic-on-ceramic implant was limited. Therefore, the level of evidence was downgraded to very low.

Zoeken en selecteren

To answer the question a systematic literature analysis was performed for the following research question:
PICO 1: What are the favourable and unfavourable effects of a total hip arthroplasty with a head diameter of 22mm, 36mm or >36 mm, compared to a toal hip arthroplasty with a head diameter of 28 or 32 mm?
P: patients planned for total hip arthroplasty;
I: total hip arthroplasty with head diameter of 22mm, 36mm or >36 mm;

C: total hip arthroplasty with head diameter of 28 or 32 mm;
O: number of revisions (both specifically for dislocation as well as for any reason)

Relevant outcome measures
The working group decided that number of revisions (both specifically for dislocation as well as for any reason) was the most important outcome measure for decision-making.

The working group did not define outcomes a priori, but used definitions as provided in the studies.

Only studies with a minimum follow-up of five years after surgery - and preferably ten years or more - were included.
The working group tried to balance the data based on the number of patients available in the original papers and the statistical analysis provided in these documents.

The working group has taken into account that one of the most important outcome measurements, the rate of dislocation, is underreported. Most dislocations are treated conservatively and are not reported in registries, unless they lead to revision of one or more prosthetic components. This is a severe methodological flaw and hence this limits the conclusions on this topic. Therefore, only revisions are included as outcome measure in this module.

Search and select (Method)
A literature search was performed with relevant search terms on 17 november 2016 in the databases Medline (OVID) and Embase (via Embase.com). The search strategy is provided in the tab "Methods". The literature search resulted in 575 hits. Studies were selected using the following selection criteria: (1) total hip arthroplasty with head diameter of 22m, 36m or >36m compared to total hip arthroplasty with head diameter of 28 or 32 mm; (2) follow-up of at least 5 years; (3) outcome reported as number of revisions (both specifically for dislocation as well as for any reason). Based on title and abstract seventeen studies were pre-selected. After obtaining full text, fifteen studies were excluded, and two studies were included in the literature analysis. In addition, data from two registries (Australian and United Kingdom) were used.

The most important study characteristics are described in evidence tables. The assessment of risk of bias is provided in risk of bias tables.

Verantwoording

Laatst beoordeeld : 12-02-2019
Laatst geautoriseerd : 12-02-2019

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

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Gecementeerde versus ongecementeerde totale heup prothese (THP)

Uitgangsvraag

Welk type prothese geniet de voorkeur?

Aanbeveling

De werkgroep adviseert om de keuze voor een heupprothese (zowel gecementeerd als ongecementeerd) te laten bepalen door de goed gedocumenteerde langere-termijneffectiviteit en de (directe en indirecte) kosten. Onder “goed gedocumenteerde langere-termijneffectiviteit” wordt verstaan: in een peer reviewed tijdschrift gepubliceerde klinische follow-up met 10-jaarsoverleving.

Voor de introductie van nieuwe, niet “goed gedocumenteerde” of gewijzigde prothesen wordt het volgende 4-stappen plan geadviseerd:

1. preklinisch onderzoek (laboratoriumtests);
2. een kleine serie operaties geëvalueerd middels radiostereometrie;
3. een gerandomiseerd klinisch onderzoek met vergelijking met een goed gedocumenteerde prothese (N $\geq$100), en tenslotte
4. bewaking van de klinische resultaten middels een implantatenregistratie

Update aanbeveling 2018: De werkgroep adviseert om de keuze voor een type heupprothese te baseren op de ODEP-benchmark, conform het NOV-advies Classificatie Orthopedische Implantaten (Link: https://www.orthopeden.org/downloads/418/classificatie-orthopedische-implantaten-werkwijze-2018.pdf).

Overwegingen

Wereldwijd bestaan er vele typen en soorten prothesen met wisselende resultaten. Gezien de commerciële belangen worden frequent nieuwe prothesen aangeboden. Deze prothesen missen vaak langdurige klinische ervaring en follow-up.

De Noorse onderzoeksgroep Aamodt et al., (2004) stelde voor, in navolging van Huiskes (1993) om nieuwe of ongedocumenteerde prothesen via een 4-stappen model te introduceren:

- preklinisch onderzoek;
- een kleine serie operaties geëvalueerd middels radiostereometrie;
- een gerandomiseerd klinisch onderzoek (n>= 100) met vergelijking met een goed gedocumenteerde prothese;
- bewaking van de klinische resultaten middels een implantatenregistratie.
  De werkgroep neemt dit voorstel over.

Het Engelse NICE instutuut (National Institute for Clinical Excellence) adviseert om heupprothesen te plaatsen die een revisiepercentage hebben van 10% of minder na minimaal tien jaar. De gegevens van deze beste prothesen moeten zijn gepubliceerd door meerdere centra in peer reviewed tijdschriften.

In deze module hebben wij geen onderscheid kunnen maken voor de keuze van de beste prothese voor jonge patiënten (<50 jaar). De reden daarvan is dat er onvoldoende publicaties bestaan die voldoen aan de NICE criteria, en waarmee een verantwoorde keuze zou kunnen worden gemaakt tussen een gecementeerde dan wel een ongecementeerde prothese. Voorts worden in studies over de ongecementeerde prothesen met een polyethyleen liner veelal onvoldoende beschreven of de liner vervangen is (en daarmee een revisie is verricht) of niet. In het Zweedse rapport van 2007 werden de jonge patiënten apart vermeld en daaruit volgde dat de overleving van zowel de gecementeerde als de ongecementeerde prothesen na tien jaar minder dan 90% bedroeg.

Inleiding

Deze module is vrijwel ongewijzigd overgenomen uit de richtlijn Totale heupprothese 2010.

Sinds vele jaren is de totale heupvervanging een succesvolle orthopedische ingreep. De klinische resultaten na totale heupvervanging zijn in het algemeen goed en de meeste patiënten functioneren uitstekend, ook op de lange termijn. Toch zijn de resultaten van alle op de markt zijn de prothesen niet met elkaar vergelijkbaar. Deze richtlijn is bedoeld als leidraad om tot een goede keuze van een te gebruiken prothese te komen. Vele factoren spelen een rol in het succes en de overleving van de prothese. Het behoeft geen betoog dat de resultaten van de totale heupvervanging in grote mate af hankelijk zijn van de vaardigheden van de chirurg. Deze module geef t een overzicht van de gecementeerde en ongecementeerde prothesen. In de literatuur wordt een onderscheid gemaakt tussen volledig gecementeerd of ongecementeerd, een gecementeerde steel met een ongecementeerde cup (hybride prothese) en de prothesen met een ongecementeerde steel en gecementeerde cup (omgekeerd hybride).

Conclusies

Niveau 1	Uit de studies van de implantatenregisters blijkt dat de resultaten van de gecementeerde totale prothesen beter zijn dan die van de ongecementeerde. Dit verschil wordt met name veroorzaakt door de slechtere resultaten van een aantal ongecementeerde acatabulumcomponenten. A2 (*The Norwegian Arthroplasty Register, 2008; Kärrholm, 2007; Australian Arthopaedic Association, 2008; National Joint Registry UK, 2007; Mäkelä, 2008)*

Niveau 3	Op basis van een modelstudie is aannemelijk gemaakt dat duurdere prothesen (veel) betere uitkomsten nodig hebben om kosteneffectief te zijn, met name in de groep patiënten van 50-70 jaar. C *Fitzpatrick, (1998)*

Samenvatting literatuur

De effectiviteit van een prothese wordt vooral uitgedrukt in overleving van de prothese (percentage nog niet gereviseerd als f unctie van de tijd), radiologisch gedrag (kenmerken voor loslating of botreactie) en heupscore (pijn en functie met gevalideerd meetinstrument). Prospectieve en gerandomiseerde gecontroleerde

onderzoeken worden beschouwd als de beste wijze om verschillende implantaten met elkaar te vergelijken. Hiervan zijn er maar weinig verschenen. De meeste onderzoeken zijn van het observationele type. Een nadeel van zowel gerandomiseerde als observationele onderzoeken is dat deze vaak door een beperkt aantal chirurgen in gespecialiseerde centra worden verricht en dat de resultaten niet zonder meer geëxtrapoleerd kunnen worden naar de algemene praktijk. Bovendien worden met grote regelmaat kleine veranderingen aan prothesen aangebracht, waarvan de ratio niet altijd duidelijk is, en die soms worden ingegeven door commerciële motieven. Zelfs de meest gedocumenteerde Charnley-prothese, veelal beschouwd als gouden standaard, onderging in de loop der jaren wijzigingen zodat in het verleden behaalde resultaten geen garantie zijn voor de resultaten van de thans in de handel zijnde prothesen. Dit geldt eens te meer omdat ook de operatietechniek in de loop der jaren is gewijzigd (bijvoorbeeld cement vacuum mixing en pressurizing).

Implantatenregister
Door de uitkomsten van nationale implantatenregistraties kan inzicht verkregen worden over het functioneren van bepaalde typen prothesen. De uitkomstparameter bij die implantatenregisters is revisie van de prothese. Een revisie betekent dat de prothese of een deel van de prothese vervangen wordt. Overigens betekent een niet-gereviseerde prothese niet dat deze ook goed functioneert. In Nederland is in 2007 een implantatenregister gestart waarvan op dit moment nog geen gegevens gepubliceerd zijn. In een aantal andere landen functioneren de registers al langere tijd en als het gaat om aantallen patiënten en follow-up duur, dan worden de resultaten in de literatuur gedomineerd door de rapporten van de Scandinavische implantatenregisters. In tabel 1 staan de meest gebruikte prothesen uit het Zweedse register met de 10-jaarsoverleving. Dit betreft de overleving van de nietgereviseerde prothesen. Niet alle in Scandinavië gebruikte prothesen zijn in Nederland op de markt en omgekeerd. Voornamelijk de ongecementeerde prothesen zijn in de Noorse en Zweedse registers ondervertegenwoordigd. Toch is er vanaf 2001 een toename in ongecementeerde prothesen van 2,6% tot 12% in 2007 in Zweden. In Australië is een toename van 21% in 2004 naar 33% in 2007 geregistreerd. In Australië was tevens een af name van gecementeerde prothesen van 53% in 2004 naar 43% in 2007 (Australian Orthopeadic Association 2008). Omdat het aantal ongecementeerde prothesen toenam voerde de Zweedse registratie een toegevoegde analyse uit. Zij vergeleek de volledig ongecementeerde f ixatie met de volledig gecementeerde (n=170.413). Hieruit bleek dat het risico op revisie voor de ongecementeerde protheses 33% hoger lag dan voor de gecementeerde. De ongecementeerde methode werd sinds 1992 vooral gebruikt bij jongere patiënten. Het risico op vroegtijdige revisie (binnen twee jaar) was dubbel zo hoog voor de ongecementeerde prothese vergeleken met de gecementeerde. Uit de Australische registratie bleek 3,8% (3,3 tot 4,3%) van de gecementeerde prothesen na zeven jaar te zijn gereviseerd en 4,4% (4,1 tot 4,8%) van de ongecementeerde. In het Engelse register was het revisierisico na drie jaar voor gecementeerd eveneens lager dan dat van de ongecementeerde prothesen (National Jount Registry UK).

In Noorwegen was het gebruik van ongecementeerde prothesen ook toegenomen. Het Noorse register adviseert tegen het gebruik van ongecementeerde cupprothesen met conventioneel polyethyleen. (The Norwegian Arthroplasty Register, 2008; Kärrholm et al., 2007). Mäkelä et al. (2008) beschreven de resultaten van het Finse implantatenregister en concludeerden dat in het algemeen gecementeerde en ongecementeerde totale heupprothesen een vergelijkbaar lange termijnresultaat hebben. Hoewel sommige ongecementeerde prothesen die geplaatst waren bij patiënten tussen de 55 en 74 jaar een betere overleving vertoonden met als eindpunt aseptische loslating, was vaak revisie vanwege het falen van de liner noodzakelijk waardoor de eindresultaten voor beide typen prothesen niet verschillend bleken te zijn.

Tabel 1: Voorbeelden van prothesen met de 10-jaarsresultaten die in het jaarrapport 2007 van het Zweedse heupregister beschreven zijn en die in de periode van 1992 tot 2007 gebruikt warden (n=184020). Overleving betekende de overleving van de steel én de cupprothese.

Prothese cup(steel)	Fixatie	Aantal	10 jr overleving (%)	95% CI
Charnley (Exeter Polished)	cement	2411	97.3%	±1.2%
CLS Spotorno (CLS Spotorno)	cementloos	1016	97.0%	±1.8%
Muller All-Poly (Muller Straight)	cement	1759	96.6%	±1.0%
Lubinus All-Poly (Lubinus SP II)	cement	60.949	96.3%	±0.3%
Charnley Elite (Lubinus SP II)	cement	1228	92.9%	±3.9%
Charnley (Charnley)	cement	23.261	92.7%	±0.4%
Exeter All-Poly (Exeter Polished)	cement	6450	92.3%	±0.4%

Meta-analysen
Door de gegevens van observationele studies en RCT's te combineren in meta-analysen is het wellicht mogelijk om een meer gegeneraliseerd beeld te krijgen van het resultaat van gecementeerde en ongecementeerde prothesen.

Faulkner et al. (1998) beschreven een review van de Health Technology Assessment (HTA) over de effectiviteit van de verschillende prothesen. Zij vonden 17 gerandomiseerde, 61 vergelijkende en 145 niet-vergelijkende observationele studies. De studies werden op methodologische kwaliteit beoordeeld. De meeste studies waren van matige tot zeer matige kwaliteit, onder andere vanwege de kleine studieomvang waardoor eventueel werkelijke bestaande verschillen tussen prothesen lang niet altijd aantoonbaar waren. Ook varieerde de follow-up duur van de diverse typen prothesen sterk. Maar het overlevingspercentage van het grote aantal gecementeerde Charnley-prothesen was gezien de lange follow-up duur (>10 jaar) interessant. Bij een follow-up duur van tien jaar bleek het overlevingspercentage iets boven de 90% te liggen. Vergelijkbare resultaten werden in de Noorse en Zweedse implantatenregisters ook voor enkele andere gecementeerde prothesen gevonden (The Norwegian Arthroplasty Register, 2008; Kärrholm et al., 2007).

In navolging van de Britse HTA-groep verrichtte een Noorse onderzoeksgroep (Aamodt et al., 2004) een systematische review van studies die werden gepubliceerd in de periode 1996 tot 2000. Zij beperkte haar review tot dié studies waarin prothesen waren onderzocht die op de Noorse markt verkrijgbaar waren. Het betrof 129 studies, waarvan 93 patiëntenseries, zes registerstudies en 30 (gecontroleerde) vergelijkende onderzoeken. In slechts 9% van de studies was sprake van randomisatie. Evenals de Britse HTA-groep stelde de Noorse onderzoeksgroep vast dat de kwaliteit van veel studies het nodige te wensen overliet. De meeste studies hadden een korte follow-up van minder dan tien jaar en bij slechts 12% van de studies was de follow-up duur langer dan 20 jaar. De Noorse onderzoeksgroep stelde dat het, gegeven de aanzienlijke verschillen in onderzoeksdesign, patiëntenpopulaties en uitkomstmaten, moeilijk was om de resultaten van de verschillende studies te vergelijken. Niettemin trok ook deze groep de conclusie dat van de meest onderzochte gecementeerdeCharnley-prothese, de 10-jaarsoverleving meer dan 90% bedroeg. In de twee daaropvolgende decennia nam het overlevingspercentage met 10% per decennium af. Betreffende de

ongecementeerdeprothesen stelde de Noorse onderzoeksgroep vast dat in geenvan de studies, waarin de resultaten met betrekking tot ongecementeerde prothesen (voor zover dus gebruikt in Noorwegen) werden beschreven, sprake was van een gemiddelde follow-up duur van 10 jaar of meer.
In een meta-analyse van Morshed et al. (2007) werd de gecementeerde fixatietechniek vergeleken met de ongecementeerde fixatietechniek. De belangrijkste uitkomstmaat was overleving van de prothese gemeten door het percentage revisies (revision rate). In totaal waren 20 studies bestudeerd. Er werd geen significant voordeel voor een van beide fixatietechnieken gevonden. De auteurs stelden dat de gecementeerde prothesen beter scoren op alle momenten maar dat ongecementeerde prothesen de laatste jaren wel betere resultaten hadden en dat bij de beoordeling van de resultaten van prothesen de leeftijd betrokken moest worden.

Ten behoeve van deze richtlijn is in de literatuur ook nog gezocht naar de resultaten van ongecementeerde prothesen in series >100 met een follow-up van meer dan 10 jaar, die in Nederland worden gebruikt en zowel in het hierboven Britse als Noorse onderzoek onderbelicht bleven. De resultaten, zoals weergegeven in onderstaande tabel, komen overeen met die van het heupregister in Finland, waar meer ongecementeerde prothesen zijn geplaatst dan in Noorwegen en Zweden. De 10-jaarsoverleving van een aantal ongecementeerde prothesen komt overeen met die van gecementeerde, maar de overleving van ongecementeerde acetabulumcups is veelal lager Eskelinen et al., (2006).

Tabel 2: Lange termijn resultaten van diverse ongecementeerde prothesen die frequent in Nederland gebruikt worden.

Auteur	Type prothese	Naam	N heupen	Follow-up (jaar)	Overleving steel (%)	Overleving cup (%)
Aldinger et al. 2003	Press fit	CLS Spotorno	326	12	95	Div. cups
Grubl et al. 2006	Press fit	Alloclassic SL – CSF	208	15,5	98	94 (alle redenen 85)
D'Antonio et al. 2001	HA coated	Omnifit -meerdere cups	314	11,1	99,5	80-97
Reikeras et al. 2003	HA coated	Landos Corail-press-fit en schroefcup	323	11	99	69-92
Pospichill et al. 2005	Press fit	Alloclassic Sl - CSF	103	14,4	100	96
Oosterbos et al. 2004	HA coated	ABG	100	10	100	97
Suckel et al. 2009	Press fit	Alloclassic SL – CSF	320	17	98,1	98,4
Garcia-Rey et al 2009	Press fit	Duraloc-HA femur	111	13,4	100	94(6liner rev)

Een economische modelstudie van een (andere) Britse HTA-groep Fitzpatrick et al., (1998) gaf aan dat de kosten bij het gebruik van een (nieuwe) prothese driemaal hoger waren dan een 'standaard-Charnley' en pas stabiliseerde als het revisiepercentage afneemt met 35% tot 44% bij patiënten tussen 50 en 70 jaar en afneemt

met 21% tot 27% bij patiënten <50 jaar. Voor patiënten ouder dan 70 jaar is –economisch - niet te verwachten dat de voordelen opwegen tegen de kosten van duurdere prothesen.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Benaderingswijze bij een totale heup prothese (THP)

Uitgangsvraag

Welke benadering geniet de voorkeur bij totale heupprothese: anterieur, posterieur of lateraal?

Aanbeveling

Zowel de posterieure, als de laterale en anterieure benadering kunnen gebruikt worden bij het plaatsen van een totale heupprothese.

Overwegingen

The differences between the three most frequently used hip approaches in The Netherlands are small in current literature. Each of the approaches has their own set of complications and benefits. Learning curves exist for all approaches and therefore proper surgical training is warranted. Surgeons are recommended to choose the approach together with the patient.

If surgeons choose the posterior approach, they should reconstruct the posterior capsule and the external rotators. This has been shown to decrease the risk of dislocation.

Inleiding

Traditionally total hip arthroplasties (THAs) are placed through the posterior, anterolateral (anterior) or the straight lateral approach. In the past decade the anterior approach has gained in popularity. In this chapter, the three most commonly used approaches in The Netherlands - the posterior, anterior and straight lateral approach - are compared in terms of complications, need for revision and functional recovery.

Conclusies

Lateral versus posterior approach

Complications (such as need for revision and dislocation)

Very low GRADE	It is unclear whether a lateral or posterior approach results in a higher risk of dislocation. *Sources (Berstock, 2015; Amlie, 2014, Mjaaland, 2017)*

Functional recovery

HOOS-scores

Very low GRADE	Functional outcome (as measured with HOOS) seems to be better for posterior than for lateral approach. *Sources Amlie, (2014)*

VAS pain

Very low GRADE	The lateral approach seems to result in more pain (as measured with the VAS-scale) than the posterior approach. *Sources Amlie, (2014)*

VAS satisfaction

Very low GRADE	The lateral approach seems to result in less satisfaction (as measured with the VAS-scale) than the posterior approach. *Sources Amlie, (2014)*

Anterior versus posterior

Complications (such as need for revision and dislocation)

Very low GRADE	There seem to be more postoperative dislocations in patients operated using the posterior than the anterior approach. *Sources (Higgins, 2015; Mjaaland, 2017; Maratt, 2016)*

Functional outcome

Very low GRADE	There seems to be no difference in functional recovery measured by unlimited walking and Harris Hip Score between the anterior and posterior approach. *Sources (Higgins, 2015; Christensen, 2015)*

Length of hospital stay

Very low GRADE	Length of hospital stay seems to be shorter for anterior approach than for posterior approach *Sources (Higgins, 2015; Christensen, 2015; Maratt, 2016)*

Anterior versus lateral

Complications (such as need for revision and dislocation)

Very low GRADE	There seems to be no difference in risk of revision due to dislocation between a lateral approach and an anterior approach. *Sources (Amlie, 2014; Mjaaland, 2017)*

Functional recovery

Very low GRADE	Functional recovery showed inconsistent results comparing the lateral approach and the anterior approach. *Sources (Amlie, 2014; De Anta Diaz, 2015)*

Samenvatting literatuur

Lateral versus posterior approach

Description of studies

Three studies were included: one meta-analysis including three RCTs and three prospective cohort studies Berstock, (2015), and two cohort studies (Amlie, 2014; Mjaaland, 2017).

Berstock (2015) included three RCTs and three prospective cohort studies (517 patients) in a systematic review and meta-analysis that compared the posterior and lateral surgical approach. Primary outcome was dislocation; functional recovery was also reported by using functional assessment scores Berstock, (2015).

In a cohort study Amlie, (2014) 1,273 patients filled out PROMs questionnaires one to three years after THA surgery. These patients were identified through the Norwegian Arthroplasty Register. Patients reported complications (such as dislocation) and patient-reported outcome measures (PROMs) including the Hip disability Osteoarthritis Outcome Score (HOOS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), health-related quality of life (EQ-5D-3L) and visual analogue scales (VAS) addressing pain and satisfaction Amlie, (2014).

Mjaaland (2017) is a cohort study from the Norwegian arthroplasty register with 21,690 THAs. MIS anterior, MIS anterolateral, posterior and direct lateral approach were compared. Outcomes reported were implant survival, and revision for any cause and specifically for infection, dislocation, femoral fracture, aseptic loosening and other causes Mjaaland,(2017).

Results

Complications (such as need for revision and dislocation)

The meta-analysis Berstock, (2015) showed that there was no difference in dislocation (odds ratio (OR) = 0.37, 95% confidence interval (CI) = 0.09 to 1.48, p-value (p)=0.16) between the posterior approach and the lateral approach.

In the cohort study by Amlie (2014), the patient self-reported dislocation rate was 3.7% for the lateral approach and 2.4% for posterolateral approach, which was not statistically significant.

Mjaaland (2017) reported a relative risk (RR) of revision due to dislocation using the posterior approach of 2.1 (95% CI = 1.5 to 3.1, p <0.001) compared to the direct lateral approach.

Functional recovery

Berstock (2015) did not report individual study results and there were not enough data to enable a meta-analysis for functional outcomes.

In the cohort study Amlie, (2014) patients filled out PROMs questionnaires one to three years after surgery. Lateral approach had worse HOOS scores for pain (adjusted mean difference = -3.6, CI = -6.3 to -0.9), other symptoms (adjusted mean difference = -3.2 , CI =-6.1 to -0.4), activities of daily living (ADL) (adjusted mean difference = -4.0, CI = -6.8 to -1.3), sport/recreation (adjusted mean difference = -4.6, CI = -8.6 to -0.6) and

quality of life (adjusted mean difference = -3.7, CI =-7.2 to -0.3). The lateral approach was associated with statistically significantly worse outcomes than the posterolateral approach on the VAS-scales for both patient satisfaction (adjusted mean difference = -4.8, CI-8.4 to -1.2) and pain in the operated hip (adjusted mean difference = -4.8, CI = -7.8 to -1.7) Amlie, (2014).

Grading of evidence

Complications (such as need for revision and dislocation)

Results of the different studies were inconsistent and mainly based on cohort studies, therefore the level of evidence was graded as very low.

Functional outcome

This was assessed in a cohort study and downgraded to very low for risk of bias.

Anterior versus posterior

Description of studies

A systematic review of 17 comparative studies Higgins, (2015) was selected, together with one RCT Christensen, (2015) and one retrospective study Maratt, (2016). Moreover, a study of Mjaaland (2017) was selected.

Higgins (2015) included 17 studies that compared the anterior with the posterior approach (two RCTs, five prospective comparative studies and ten retrospective comparative studies). Reported outcomes were dislocation rate and validated patient-reported outcome measures (pain, functioning); secondary outcomes were intra-operative, post-operative and radiographic comparisons. Follow-up ranged from direct postoperative to two years Higgins, (2015).

Christensen (2015) conducted a RCT in 51 patients that compared functional recovery during the early postoperative period (6 weeks) after direct anterior and posterior approaches. Outcomes measured were length of hospital stay, pain score and functional recovery Christensen, (2015).

Maratt (2016) retrospectively compared the direct anterior approach for a THA with a posterior approach. In total 2147 patients who underwent the direct anterior approach were propensity score matched with 2147 patients who underwent a posterior approach. Outcomes measured were dislocation rate and complications such as fractures and hematomas within 90 days Maratt, (2016).

Mjaaland (2017) is a cohort study from the Norwegian arthroplasty register with 21,690 THAs. MIS anterior, MIS anterolateral, posterior and direct lateral approach were compared. Outcomes reported were implant survival, revisions for any cause and specifically for infection, dislocation, femoral fracture, aseptic loosening and other causes Mjaaland, (2017).

Results

Complications (such as need for revision and dislocation)

Higgins (2015) estimated the Peto odds ratio and showed a pooled (fixed) effect of 0.29 (95% CI = 0.09-0.95, p-value (p) = 0.04) favouring the anterior approach. In this analysis 728 patients (two dislocations) who underwent an anterior approach were compared with 745 patients (nine dislocations) who were operated using the posterior approach Higgins, (2015).

Maratt (2016) showed no difference in dislocation rate, which was 0.84% for the anterior approach versus 0.79% for the posterior approach (P=0.88) Maratt, (2016).

Mjaaland (2017) does not report a direct comparison between anterior versus posterior approach but reports relative risks of minimally invasive surgery (MIS) anterior/anterolateral and posterior approach compared to direct lateral. The relative risk of revision due to dislocation (154 patients) using the posterior approach was 2.1 (95% CI = 1.5 to 3.1, p<0.001) compared to the direct lateral approach. The relatieve risk for the MIS anterior and MIS anterolateral approaches compared with the direct lateral approach was 0.71 (95% CI = 0.40 to 1.3, p = 0.25) Mjaaland, (2017).

Functional recovery

One RCT included in the systematics review of Higgins (2015) reported patient-reported pain (visual analogue scale (VAS)) and function (Harris Hip Score (HHS) and Hip disability and Osteoarthritis Outcome Score (HOOS)). Early functional results favoured the anterior approach, there was no difference on the longer term. There was no difference in pain between the two approaches. The other prospective and retrospective studies in Higgins' review showed little or no difference in functional outcome Higgins, (2015).

A randomized controlled trial of Christensen (2015) reported greater pain relief after surgery was in the anterior group (P=0.04), none of the other functional measures differed between the two groups. There were no differences in Harris Hip Scores after six weeks Christensen, (2015).

Length of stay (LOS)

The study of Higgins (2015) reporter shorter length of hospital stay in the anterior group compared to the posterior approach (mean difference = -0.53, 95%CI = -1.01 to -0.04).

The RCT of Christensen (2015) showed that length of hospital stay was significantly shorter for the anterior approach than the posterior approach (1.4 versus 2.0 days, p=0.01).

A retrospective study of Maratt (2016) did not find a difference in length of hospital stay between the anterior and the posterior approach (2.37 versus 2.54 days, P=0.28).

Grading of evidence

Complications (such as need for revision and dislocation)

Evidence of the systematic review was graded as very low due to high risk of bias and because of heterogeneity.

Functional outcome

This was estimated based on one RCT and two cohort studies with a high risk of bias and a retrospective analysis and graded as very low, because of hetereogeneity.

Length of stay

Evidence of the systematic review was graded as low due to high risk of bias, for the outcome length of hospital stay it was graded as very low because of high heterogeneity.

Description of studies

Three studies compared the anterior with lateral approach (Amlie, 2014; De Anta Diaz, 2015, Mjaaland, 2017).

In a cohort study Amlie, (2014) 1273 patients filled out Patient Reported Outcome Measures (PROMs) questionnaires one to three years after THA surgery. These patients were identified through the Norwegian Arthroplasty Register. Patients reported complications such as dislocation, and pPROMs including the Hip disability Osteoarthritis Outcome Score (HOOS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), health-related quality of life (EQ-5D-3L), and visual analog scales (VAS) addressing pain and satisfaction Amlie, (2014).

De Anta Diaz (2015) was a RCT study of 49 patients who received a direct anterior THA and 50 patients who received a lateral approachTHA. Outcomes reported were muscle damage and functional recovery De Anta Diaz, (2015).

Mjaaland (2017) is a cohort study from a registry with 21,690 THAs. MIS anterior, MIS anterolateral, posterior and direct lateral approach were compared. Outcomes reported were implant survival, revisions for any cause and femoral fractures Mjaaland, (2017).

Results

Complications (such as need for revision and dislocation)

Self-reported dislocation was 3.7% for lateral approach and 3.1% for anterior approach; this difference was not statistically significant Amlie, (2014). Mjaaland (2017) found no difference in dislocation. The RR of revision due to dislocation using the anterior/anterolateral approach compared to the direct lateral approach was 0.71 (95% CI = 0.40 to 1.30, p=0.25) Amlie, (2014).

Functional recovery

The cohort study Amlie, (2014) had the following results. Lateral approach scored worse on HOOS scores for pain (adjusted mean difference = -3.6, CI =-6.1 to -1.1), other symptoms (adjusted mean difference = -3.8, CI = -6.5 to -1.1), ADL (adjusted mean difference = -4.8, CI = -7.3 to -2.2), sport/recreation (adjusted mean difference = -4.8, CI =-8.6 to -1.0) and quality of life (adjusted mean difference = -5.0, CI =-8.3 to -1.8). The lateral approach was associated with statistically significantly worse outcomes than the anterior approach on the VAS for both patient satisfaction (adjusted mean difference = -3.8, CI = -7.2 to -0.4) and pain in the operated hip (adjusted mean difference = -3.9, CI = -6.9 to -1.1) Amlie, (2014).

One RCT compared the anterior with the lateral approach. It showed no difference in Harris Hip Scores (96.2 versus 94.5) De Anta Diaz, (2015).

Grading of evidence

Complications (such as need for revision and dislocation)
Evidence was graded as very low as there were two cohort studies used here that had heterogeneous results.

Functional recovery
The level of evidence started as low (observational study) and was downgraded to very low because of risk of bias.

Zoeken en selecteren

To answer the question a systematic literature analysis was done for the following research question:

PICO 1: What are the effects of a posterior approach, compared to a lateral approach, for total hip prosthesis in adult patients?
P: adult patients with total hip prosthesis;
I: posterior approach;
C: lateral approach;
O: complications (such as need for revision and dislocation) and functional recovery.

PICO 2: What are the effects of an anterior approach, compared to a posterior or lateral approach, for total hip prosthesis in adult patients?
P: adult patients with total hip prosthesis;
I: anterior approach;
C: posterior or lateral approach;
O: complications (such as need for revision and dislocation) and functional recovery.

Relevant outcome measures
The working group decided that complications such as dislocation and need for revision were critical outcome measures for decision-making and postoperative functional recovery was important for decision-making.

Search and select (Method)
A literature search was performed with relevant search terms on 23 january 2017 in the databases Medline (OVID) and Embase. The search strategy is provided in the tab "Methods". The literature search resulted in 632 hits. Studies were selected using the following selection criteria: using an anterior, posterior or lateral approach for total hip arthroplasty (THA), describing at least one of the selected outcome measures and including at least 50 patients. Based on title and abstract 33 studies were preselected. After obtaining full text, 25 studies were excluded (see exclusion table) and eight studies were included in the literature analysis.

The most important study characteristics are described in evidence tables. The assessment of risk of bias is provided in risk of bias tables.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

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Tromboseprofylaxe bij een totale heup prothese (THP)

Deze module is onderverdeeld in twee submodules waarin de volgende uitgangsvragen worden behandeld:

1. Wat is het optimale tijdstip om tromboseprofylaxe te starten rondom grote orthopedische/ traumatologische ingrepen?
2. Wat is de optimale vorm en duur van tromboseprofylaxe na grote orthopedische/ traumatologische ingrepen?

Verantwoording

Laatst beoordeeld : 12-02-2019
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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Timing van tromboseprofylaxe bij een totale heup prothese (THP)

The working group refers to the module ‘start van tromboseprofylaxe bij grote orthopedische en traumatologische ingrepen trombose’ (Guideline ‘Antitrombotisch beleid’) for recommendations about the optimal timing to start thrombosis prophylaxis around total hip arthroplasty: https://richtlijnendatabase.nl/richtlijn/antitrombotisch_beleid/preventie_vte/start_profylaxe_grote_orthopedische

Verantwoording

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Keuze en duur van tromboseprofylaxe bij een totale heup prothese (THP)

The working group refers to the module ‘start van tromboseprofylaxe bij grote orthopedische en traumatologische ingrepen trombose’ (Guideline ‘Antitrombotisch beleid’) for recommendations about the optimal timing to start thrombosis prophylaxis around total hip arthroplasty: https://richtlijnendatabase.nl/richtlijn/antitrombotisch_beleid/preventie_vte/start_profylaxe_grote_orthopedische

Verantwoording

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Perioperatieve zorg bij een primaire totale heup prothese (THP)

Deze module is onderverdeeld in drie submodules waarin de volgende uitgangsvragen worden behandeld:

1. Wat is het beleid met betrekking tot systemische antibiotica ter preventie van postoperatieve wondinfectie?
2. Wat is de plaats van antibioticumhoudend botcement?
3. Wat is het beleid met betrekking tot het gebruik van een combinatie van mupirocine en chloorhexidine in patiënten die een totale heupprothese ontvangen?

Verantwoording

Laatst beoordeeld : 12-02-2019
Laatst geautoriseerd : 12-02-2019

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Systemische antibioticum profyaxe bij een totale heup prothese (THP)

Uitgangsvraag

Wat is het beleid met betrekking tot systemische antibiotica ter preventie van postoperatieve wondinfectie?

Aanbeveling

Geef bij implantatie van een totale heupprothese altijd systemische antibioticum profyaxe, en kies voor cefazoline (kefzol) 2 gram i.v., 15 tot 60 minuten voor incisie.

Indien BMI >40 kg/m^2 en/of lichaamsgewicht >130 kg, geef cefazoline (kefzol) 3 gram i.v., 15 to 60 minuten voor de incisie.

Geef een hernieuwde dosering (cefazoline 1 gram i.v.) bij operatieduur van 4 uur of meer en bij bloedverlies van >1500 milliliter.

Indien gekozen wordt voor 24 uur antibiotica profylaxe, geef dan in geval van cefazoline postoperatief 1 gram na 8 en na 16 uur (NB maximale dosering 6 gram/24 uur).

Geef de antibiotica profylaxe niet langer dan 24 uur.

Let op bij nierfunctiestoornis: geef bij een klaring 10 tot 34 postoperatief cefazoline 500 milligram na 12 uur; bij een klaring <10 geen postoperatieve gift).

Geef bij allergie voor cefalosporines: clindamycine 600 milligram (>180 kilogram: 900 milligram), 15 tot 60 minuten voor incisie. Geef een hernieuwde dosering (clindamycine 600 milligram i.v.) bij een operatieduur van 6 uur of meer en bij bloedverlies van >1500 milliliter.

Als gekozen wordt voor 24 uurs antibioticaprofylaxe: geef dan postoperatief 600 milligram na 8 en na 16 uur (clindamycine dosering onafhankelijk van nierfunctie).
Een alternatief voor clindamycine is vancomycine 1 gram i.v. (>100 kilogram 10 milligram/kilogram), start 60 tot 120 minuten voor incisie. Geef een hernieuwde dosering (vancomycine 1 gram i.v.) bij een operatieduur van meer dan 8 uur en bij bloedverlies van >1500 milliliter. Als gekozen wordt voor 24 uurs antibioticaprofylaxe: herhaal 1 gram i.v. na 12 uur*** (bij klaring <50: geen tweede gift).

***(uitgaande van dagdosering 2000 milligram)

Overwegingen

Given the enormous consequences of prosthetic joint infections, a low threshold for antibiotic prophylaxis is required. The antibiotic prophylaxis should cover the main causes of infections after total hip arthroplasty.

Stichting Werkgroep Antibiotica Beleid (SWAB) is a Dutch organisation involved in optimising the use of

antibiotics, amongst others by developing guidelines. The guideline “peri-operatieve profylaxe”, is a generally accepted guideline, on which recommendations regarding choice, dosage and duration in this guideline are based.

According to the SWAB guideline, cefazolin 2 grams i.v., is administered in a single dose 30 to 60 minutes before incision. A study by Van Kasteren et al. (2007) showed less SSI if antibiotic prophylaxis was given 1 to 30 and 30 to 60 minutes before incision. This finding was the reason that in the Netherlands the policy to administer antibiotics 15 to 60 minutes before operation has generally been implemented as part of a nationwide hospital safety management program; the performance of each hospital on this subject is annually checked by the Health and Youth Care Inspectorate.

Use 3 grams if BMI is over 40 and/or if bodyweight is over 130 kilograms.

Since it is standing practice (90% of hospitals) to provide antibiotic prophylaxis for 24 hours in orthopaedic implant surgery this single dose is generally followed by additional doses of 1 gram 8 and 16 hours after the preoperative dose. Limited evidence exists regarding a difference in outcome between a single dose and 24 hours in favour of the latter. Administration for longer than 24 hours has no additive value Engesaeter, (2003).

In case the patient has a history of a rash in response to a penicillin (amoxicillin et cetera), the chance of an adverse reaction to a cephalosporin is very small and cefazolin can be given Engesaeter, (2003).

In case the patient has a history of an IgE-mediated reaction (or a direct reaction) to a penicillin - like pruritus, urticaria, angioedema, laryngeal edema - cephalosporins are contra-indicated and alternatives are: clindamycin 600 miligrams (>180 kilograms: 900 miligrams), 15 to 60 minutes before incision, or vancomycin 1 gram i.v. (>100 kilograms: 10 miligrams/kilograms), start infusion 60 to 120 minutes before incision. In case of known MRSA carriership vancomycin is advised Engesaeter, (2003).

Inleiding

The percentage of deep surgical wound infection after total hip arthroplasty (THA) in the Netherlands in the period 2012 to 2016 was 1.2% (1,162/100,254) (RIVM, 2017). Although THA is regarded as “clean surgery”, due to the severe consequences of these infections administration of systemic antibiotic prophylaxis is indicated. The antibiotic used for prophylaxis should be effective against the main bacterial causes and optimising the timing and dosage are essential to achieve the optimal concentration during the procedure, to prevent infection of the prosthesis.

Conclusies

Low GRADE	Systemic antibiotics, compared to placebo, seem to decrease the risk of infection after total hip arthroplasty. *Sources (AlBuhairan, 2008; Voigt, 2015)*

Samenvatting literatuur

Description of studies
Two studies were included in this literature summary (see the evidence table) (Voigt, 2015; AlBuhairan, 2008). One study on pre-operative systemic antibiotics and antiseptics included a meta-analysis of three RCTs on pre-operative systemic antibiotics (N=1176) compared to placebo (N=1172) for hip replacement. Main outcome reported was infection at six months Voigt, (2015).

Another study, also included in the previous guideline, included seven RCTs (3065 patients) AlBuhairan, (2008).

Results
Infection risk
The study of Voigt (2015) showed that systemic antibiotics, compared to a placebo decreased the risk of infection after total hip prosthesis at six months (RR 0.23; 95%CI 0.12 to 0.43).

In the study of AlBuhairan (2018), the administration of antibiotics reduced the relative risk (RR) of wound infection by 81% (RR 0.19; 95% CI 0.12 to 0.31; chi-squared test, p<0.00001). Because such events are rare, this translates to an absolute risk reduction of 8%, meaning that one wound infection would be prevented for every 13 people treated compared with no administration of antibiotics (risk difference -0.08; 95% CI -0.03 to -0.12) AlBuhairan, (2008).

Grading of evidence
Infection risk
The evidence was graded as low, because there was not enough information provided in the RCTs to evaluate their quality regarding randomisation procedure and allocation concealment, and outcome assessors were not blinded to group assessment (risk of bias). Moreover, the study reported also broad confidence intervals (imprecision).

Zoeken en selecteren

To answer the question a systematic literature analysis was performed for the following research question:

What are the favourable and unfavourable effects of systemic antibiotics, compared to no antibiotics, in patients selected for total hip arthroplasty?
P: patients selected for total hip arthroplasty;
I: systemic antibiotic;
C: no antibiotics;
O: surgical site infection;

Relevant outcome measures
The working group decided that surgical site infections were critical outcome measure for decision making.

The working group defined any decrease of deep infections as clinically relevant.

Search and select (Method)
A literature search was performed with relevant search terms on november 23 2016 in the databases Medline

(via OVID) and Embase (via Embase.com). The search strategy is provided in the tab "Methods". The literature search resulted in 209 hits. Studies were selected using the following selection criteria: original article, systematic review or meta-analysis; relevant to the question. Based on title and abstract 14 studies were preselected. After obtaining full text, thirteen studies were excluded (see exclusion table) and one study was included in literature analysis. Another study, included in the previous guideline, also fulfilled the PICO and was added to the literature summary.

The most important study characteristics are described in evidence tables. The assessment of risk of bias is provided in risk of bias tables.

Verantwoording

Laatst beoordeeld : 12-02-2019
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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

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Antibioticumhoudend botcement bij een totale heup prothese (THP)

Uitgangsvraag

Wat is de plaats van antibioticumhoudend botcement?

Aanbeveling

Gebruik bij implantatie van primaire gecementeerde totale heupprothese altijd een antibioticumhoudend cement (in combinatie met systemische antibioticumprofylaxe).

Overwegingen

The most commonly used antibiotic in cement is gentamicin, which is commercially available and has broad-spectrum activity and is effective against the main bacterial causes of deep infection. Since revision risk is lowest if antibiotic-impregnated cement is combined with systemic antibiotic prophylaxis, as shown by Engeseater (2003), the working group recommends always using systemic antibiotic prophylaxis too.

Inleiding

If bone cement is used in total joint arthroplasty, in the Netherlands the advice is to use antibiotic-loaded cement as standard of care. This facilitates the local release of antibiotics, leading to a higher local concentration, with the aim to reduce the rate of deep infection Wang, (2013). The type of antibiotic used in bone cement should be effective against the main bacterial causes of deep infection.

Conclusies

Risk of superficial infection

High GRADE	Antibiotic-impregnated bone cement did not decrease the rate of **superficial** infection compared to plain bone cement in patients undergoing hip or knee arthroplasty. *Sources Wang, (2012)*

Risk of deep infection

High GRADE	Antibiotic-impregnated bone cement leads to fewer **deep wound** infections than non-antibiotic-impregnated bone cement in patients undergoing hip or knee arthroplasty. *Sources (Parvizi, 2008; Wang, 2012)*

Revision risk

Low GRADE	Revision risk seems to be lower for antibiotic-impregnated bone cement compared to non-antibiotic-impregnated bone cement in patients undergoing total hip arthroplasty. *Sources (Engesaeter, 2003; Colas, 2015)*

Samenvatting literatuur

Three new studies were included to answer this question, two meta-analyses and a cohort study (Parvizi, 2008; Wang, 2012; Colas, 2015). Also a registry study included in the 2010 guideline was added to the literature summary Engesaeter, (2003).

The meta-analysis by Parvizi (2008) included six RCTs (Lynch, 1987, Josefsson, 1990, Josefsson and Kolmert, 1993; Havelin, 1995; Espehaug, 1997), comprising 24,661 THAs (primary and revision hip arthroplasty) comparing antibiotic impregnated cement (gentamicin) with non-antibiotic impregnated cement. Data with regard to the use of systemic antibiotics prophylaxis was limited. Outcomes required for inclusion in the meta-analysis were the incidence of deep infection and the overall survival rate at the specified interval after surgery Parvizi, (2008).

The meta-analysis by Wang (2013) included eight RCTs (Pfarr, 1979; Wannske, 1979; Josefsson, 1981; Bohm, 2012; Chiu, 2000; Hinarejos, 2013; McQueen, 1987; McQueen, 1990), regarding patients undergoing primary total hip arthroplasty (Pfarr, 1979; Wannske, 1979; Josefsson, 1981; Bohm, 2012) or total knee arthroplasty (Chiu, 2000; Hinarejos, 2013;), or both (McQueen, 1987; McQueen, 1990). All these studies included an antibiotic-impregnated bone cement trial group and a control group that involved the use of plain bone cement or systemic antibiotics prophylaxis. Outcomes reported were superficial and deep wound infection Wang, (2013).

The cohort study of Colas (2015) included 107,382 patients that had undergone a THA for rheumatoid arthritis. It compared revision risk between implants with antibiotic-impregnated cement (21.4%), and either uncemented (74.8%), or antibiotic free cemented implants (3.8%). Median follow-up was 33 months Colas, (2015). The outcome reported was revision risk Colas, (2015).

The registry study of Engesaeter (2003; included in the 2010 guideline) included 22,170 THAs. Patients had received systemic antibiotic prophylaxis with a cephalosporin or a penicillin combined with antibiotic impregnated bone cement in 71% of the cases. These patients were compared with those who had received only systemic antibiotics (27%). Main outcome reported was revision risk Engesaeter, (2003).

Results

Risk of superficial infection

In the study by Wang (2013) no statistically significant difference was found in risk of superficial infection between antibiotic impregnated cement compared to plain bone cement (RR = 1.42; 95% CI 0.81 to 2.50; *P*= 0.22).

Risk of deep infection

Parvizi (2008) found a weighted mean effect of 0.506 (95% CI (0.341 to 0.751)), p=0.001 for antibiotic cement in reducing the risk of infection in primary THA.

Meta-analysis of the cumulative data from all studies confirmed the efficacy of antibiotic cement in reducing the rate of deep infection in primary THA from 2.3% when no antibiotic was present in the cement to 1.2% with the use of antibiotic cement Parvizi, (2008).

Wang (2013) found a Risk Ratio of 0.34 (95%CI (0.07; 1.58)) for antibiotic cement for deep infection compared to plain bone cement in both hip and knee surgery. A risk ratio of 0.37 (95% CI (0.14 to 0.98)) was found for antibiotic cement for deep infection compared to systemic antibiotics in both hip and knee surgery. In the subgroup of patients undergoing hip arthroplasty, the risk ratio for a deep infection was 0.21 (95%CI (0.08; 0.5)) for antibiotic cement compared to plain cement Wang, (2013).

Revision risk
Colas (2015) showed that antibiotic-impregnated cemented total hip arthroplasties had a better prognosis than uncemented total hip arthroplasties: cumulative revision rates were 2.4% and 3.3%, respectively (P<0.001) and the multivariate adjusted hazard ratio was 0.74 (95%CI, 0.67 to 0.84; P<0.001) Colas, (2015).

The registry study by Engesaeter (2003) found that revision risk was 1.4 times higher for those who received antibiotics only systemically, as compared to a combined strategy of systemic antibiotics and impregnated bone cement (P<0.001).

Grading of evidence
Risk of superficial infection
For this analysis a meta-analysis of five RCTs was used, the level of evidence was considered high quality.

Risk of deep infection
Infection results are based on two meta-analysis of RCTs. Results pointed in the same direction, the level of evidence was not decreased and considered high quality.

Revision risk
Revision risk was studied in a cohort study and a registry, the level of evidence was considered low quality.

Zoeken en selecteren

To answer the question a systematic literature analysis was performed for the following research question:
What are the effects of antibiotic containing bone cement, compared to bone cement without antibiotics, in primary total hip arthroplasty for arthrosis or avascular necrosis?
P: primary total hip arthroplasty for arthrosis or avascular necrosis;
I: antibiotic containing bone cement;
C: bone cement without antibiotics;
O: superficial wound infection, deep wound infection, revision risk.

Relevant outcome measures
The working group decided that deep wound infection were critical outcome measures for decision making, and regarded superficial wound infection and revision risk as important outcome measures. Any significant difference in infection risk is considered clinically relevant.

Search and select (Method)
A literature search was performed with relevant search terms on December 15 2016 in the databases Medline (via OVID) and Embase (via Embase.com). The search strategy is provided in the tab "Methods". The literature search resulted in 221 hits. Studies were selected using the following selection criteria: addressing the research question, methodological quality, randomised controlled trial, systematic review, meta-analysis, or registry study. Based on title and abstract 16 studies were preselected. After obtaining full text, thirteen studies were excluded (see exclusion table) and three studies were included in literature analysis (Parvizi, 2008; Wang, 2013; Colas, 2015). Also a registry study included in the 2010 guideline was added to the literature summary Engesaeter, (2003).

The most important study characteristics are described in evidence tables. The assessment of risk of bias is provided in risk of bias tables.

Verantwoording

Laatst beoordeeld : 12-02-2019
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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

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Preoperatieve dekolonisatie bij een totale heup prothese (THP)

Uitgangsvraag

Wat is het beleid met betrekking tot het gebruik van een combinatie van mupirocine en chloorhexidine in patiënten die een totale heupprothese ontvangen?

Aanbeveling

Op basis van de literatuur heeft de werkgroep onvoldoende argumenten om enigerlei aanbeveling te doen omtrent preoperatieve screening op S. aureus en dekolonisatie met mupirocine en chloorhexidine bij patiënten die een totale heuparthroplastiek ondergaan.

Overwegingen

There is a minimal reduction of SSI by prophylactic use of mupirocin/chlorhexidine in all patients compared to selective use; selective use shows minimally reduced SSI compared to no use. The level of evidence for this reduction in SSI is very low grade because it is based on only a few cohort studies without any randomised controlled trials. The overall infection percentages of any regimen reports are well below 2%, so potential benefits are marginal at best.

It is questionable whether the study results mentioned can be extrapolated to the Netherlands since they are performed in countries with a much higher MRSA prevalence and the results may differ from our situation.

Furthermore, the studies performed are of heterogeneous nature regarding inclusion criteria and outcome reporting. In the studies it is not clearly stated what the procedures were for screening carriership and what the exact regimens of decolonisation were.

Another weakness is that it is unclear what the adherence to treatment was of all patients. Also in many studies, as a consequence of the screening for MRSA/MSSA, patients in the intervention group received a more adequate antibiotic prophylaxis (vancomycin in case of MRSA carriage), whilst in the control group, this carriage was unknown. In joint arthroplasty surgery other micro-organisms, like Coagulase Negative Staphylococci are also known to be important causes of implant infections.

With the current limited data it is impossible to calculate exactly the cost effectiveness of any approach. The costs of logistics, mupirocin, chlorhexidine, screening by PCR, costs of infection treatment and loss of labour participation are all involved, as well as the burden to the patients of infection treatment. Standard application to all patients undergoing THA may result in increased mupirocin resistance and unnecessary costs; screening patients may be beneficial in reducing resistance, but has its costs and logistical burden too.

In conclusion, based on the literature there is insufficient evidence to support the SWAB guideline regarding screening and decolonization of *S. aureus* with mupirocin and chlorhexidine in patients undergoing total hip arthroplasty.

Inleiding

Staphylococcus aureus is an important cause of post-surgical wound infections and the use of intranasal mupirocin in carriers may decrease the rate of *S. aureus* infections in surgical patients.

Guidelines such as the "Clinical practice guidelines for antimicrobial prophylaxis in surgery" by the IDSA recommend application of mupirocin intranasally for all patients known to be colonised with *S. aureus* and undergoing joint arthroplasty Bratzler et al., (2013). Also, the SWAB guideline on surgical prophylaxis recommends screening patients undergoing orthopaedic implantation surgery and in the case of a positive result for *S. aureus*, to apply both mupirocin and chlorhexidine pre-operatively, but with an exception for centres with very low infection rates.

Nowadays in Dutch hospitals, there are different approaches, some hospitals do not have a mupirocin protocol in orthopaedic implantation surgery, there are hospitals that only apply mupirocin to *S. aureus* carriers and in other hospitals all patients receive mupirocin before implantation. This lack of uniformity is undesirable, as it could result in suboptimal prevention measures, or lead to unnecessary use of mupirocin, which may cause induction of resistance and unnecessary costs.

A literature study was performed to assess the influence on infection rates of prophylactic mupirocin and chlorhexidine body wash, applied to all patients undergoing joint arthroplasty, to *S. aureus* carriers only, or to no patients at all.

Conclusies

Category 1

Very low GRADE	Screening for *S. aureus* carriership and subsequent application of mupirocin and chlorhexidine pre-operatively, combined with adapted systemic prophylaxis if MRSA was detected, compared to a historical control group, seems to be associated with a lower amount of SSI. *Sources (Baratz, 2015; Rao, 2010; Sporer, 2016; Schweizer, 2015)*

Category 2

Very low GRADE	Application of mupirocin and chlorhexidine to all patients, compared to screening and application on indication, seems to be associated with a lower amount of SSI in patients who undergo total hip arthroplasty. *Sources Stambough, (2016)*

Category 3

Very low GRADE	Screening and pre-operative decolonisation of *S. aureus* with mupirocin and chlorhexidine on indication, compared to no application of mupirocin seems to be associated with a lower amount of revision due to infections in patients who underwent total joint arthroplasty. *Sources Malcolm, (2016)*

Samenvatting literatuur

Description of studies
Five studies were included, which compared the differences in SSIs between a group of patients who were screened and treated according to a decolonisation protocol, compared to a control group (Baratz, 2015; Rao, 2011; Schweizer, 2015; Sporer, 2016; Stambough, 2016). One study was included, which investigated whether there is a difference in amount of revisions between a group of patients who were screened and treated according to a decolonisation protocol, compared to a control group Malcolm, (2016).

Because of heterogeneity in screening and decolonisation protocols used, the studies, their results and conclusions are described in three categories:

- *Category 1* included studies that investigated the number of SSIs after screening and application of mupirocin and chlorhexidine on indication compared to a (historical) control group with unknown history regarding application of mupirocin and/or chlorhexidine.
- *Category 2* included studies that investigated the number of SSIs after screening and application of mupirocin and chlorhexidine body wash on indication, compared to application of mupirocin and chlorhexidine body wash to all patients undergoing total joint arthroplasty.
- *Category 3* included studies that investigated the number of revisions due to SSIs after screening and application of mupirocin and chlorhexidine on indication, compared to application of chlorhexidine only.

Characteristics of included studies:
Category 1
In four studies regarding patients undergoing total joint arthroplasty the differences in number of SSIs after screening and application of mupirocin and chlorhexidine on indication were compared to a (historical) control group with unknown history regarding mupirocin and/or chlorhexidine (Baratz, 2015; Rao, 2011; Schweizer, 2015; Sporer, 2016). Some studies included patients in the intervention group who were not screened before surgery. These patients were all treated with mupirocin and chlorhexidine until screening results were known.

The retrospective clinical study by Baratz (2015) compared the infection risks of a group of patients who were screened and treated according to a decolonisation protocol (intervention group) to a historical control cohort (control group) after elective total joint arthroplasty Baratz, (2015).

In the intervention group, all patients were screened for nasal carriage of MSSA or MRSA pre-operatively. Carriers were treated with mupirocin intranasally (Bactroban; GlaxoSmithKline, Middlesex, UK) and chlorhexidine soap for five days, including the day of surgery. A first-generation cephalosporin (cefazolin) was given as systemic prophylaxis and patients with a β-lactam allergy received vancomycin. In addition to cefazolin, carriers of MRSA received vancomycin.

A patient group from a 2-year period (January 2009 to December 2010) before the implementation of the screening and decolonisation protocol was included as a control Baratz, (2015).

The intervention group consisted of patients who underwent primary (n = 2903) or aseptic revision (n = 531) total hip or knee arthroplasty (THA or TKA). In the intervention group, 158 patients (5%) tested positive for MRSA and 508 patients (15%) were positive for MSSA. The control group consisted of 3080 patients (primary cases, n = 2515; revision cases, n = 567). SSIs were defined according to the National Healthcare Safety Network guidelines of the Center for Disease Control and Prevention. No baseline values were given Baratz, (2015).

The prospective cohort study by Rao (2011) investigated the number of SSIs in patients who underwent elective total joint arthroplasty. The intervention group (n = 1440) was compared with two control groups. One concurrent control group with surgical patients who did not participate in the screening and decolonisation protocol (n = 2284) and a pre-intervention control group (n = 741) in which patients were included who underwent TJA one year before the implementation of a decolonisation protocol. No details were given regarding inclusion criteria for the pre-intervention control group, concurrent control and intervention group. Also no information is available regarding systemic prophylaxis or the use of chlorhexidine in the control groups Rao, (2011).

Patients in the intervention group were screened two to four weeks before surgery. Carriers of *S. aureus* used mupirocin nasal ointment two times per day for five days and had chlorhexidine baths daily for five days. This protocol started five days before surgery. All patients received peri-operative antibiotic prophylaxis with cefazolin, or in case of MRSA carriers or a history of MRSA or type I allergy to penicillin, vancomycin was given. In the intervention group, 321 participants were carriers of *S. aureus* (MSSA = 278; MRSA = 43). The reported outcome measure was SSI, with a follow-up of two years after total joint arthroplasty. No baseline values were given Rao, (2011).

The quasi-experimental pragmatic study by Schweizer (2015) compared the risk of SSIs in patients undergoing primary hip or knee arthroplasty (and cardiac operations) between a group of patients who were screened and treated according to a decolonisation protocol (intervention group) and a historical control group. In total 31,701 operations, performed in 20 hospitals (8 hospitals implemented the bundle for joint arthroplasties, 4 for cardiac operations, and 8 for both categories), were included (n pre-intervention = 20,642; n intervention = 11,059). Hospitals that implemented parts of the intervention during the pre-intervention period were allowed to participate Schweizer, (2015).

Patients in the intervention group were screened for *S. aureus* 10 to 14 days before surgery (no more than 30 days). Carriers of MRSA or MSSA received mupirocin intranasally twice daily for five days and bathed with chlorhexidine once daily for five days immediately before surgery. Patients with negative screening for MRSA or MSSA bathed with chlorhexidine the night and morning before operation. Patients received cefazolin or cefuroxime as peri-operative prophylaxis and in case of MRSA carriership, vancomycin was added. In case of β-lactam allergy, a combination of vancomycin and gentamicin or aztreonam was given. Patients with history of MRSA, but negative screening were treated as carriers. Patients who were not screened or whose screening results were not known received vancomycin and cefazolin or cefuroxime and decolonisation was started immediately before their operation. Mupirocin was discontinued if test results were negative. There were some

differences in baseline values. The intervention group was younger, had lower CCI scores, and were less likely to have a history of MRSA carriership compared to the control group. The primary outcome measure was the amount of complex MSSA or MRSA SSIs Schweizer, (2015).

The observational study by Sporer (2016) investigated the effect of a screening and decolonisation protocol on the risk of SSIs in participants who underwent total hip or knee arthroplasty. The treatment protocol came into effect on January 1, 2009. Patients who underwent total joint arthroplasty between 2008 and 2009 were included in the control group (n=1440). The intervention group consisted of 9825 participants. In the intervention group, 98.6% of the patients underwent screening, 2.9% had a positive screening for MRSA and 25.1% for MSSA Sporer, (2016).

All patients in the intervention group were screened at least 14 days before surgery. Carriers of MSSA or MRSA were treated with 2% mupirocin ointment (Bactroban; GlaxoSmithKline, Middlesex, United Kingdom) and 2% chlorhexidine gluconate showers for five days before admission to the hospital. Cefazolin was given as antibiotic prophylaxis. MRSA patients received vancomycin, all other *S. aureus*–positive patients received cefazolin. Patients identified with MSSA or MRSA less than five days before admission were instructed to take showers with chlorhexidine until admission and also mupirocin until completion of 10 doses. Patients with unknown colonisation status were screened on day of admission and received mupirocin immediately before surgery and until the screening results were negative for MSSA or MRSA, or the patient had completed 10 doses. All patients, regardless of nasal colonisation, were instructed to shower the night before the operation and apply chlorhexidine, this was repeated on the morning of surgery. Peri-operative infection rates were compared from 1 year before implementation to 5 years after implementation of the screening protocol. The study mentioned that surgical skin preparation, administration of prophylactic antibiotics and environmental conditions in the operating room were not different between the control and intervention group. SSIs were monitored by the hospital within 30 days after index surgery. The criteria of the Centers for Disease Control and Prevention were used to identify SSI Sporer, (2016).

Category 2

In one study, the differences in number of SSIs in patients undergoing THA were compared between the application of mupirocin and chlorhexidine to all, or after entering a screening programme and application on indication Stambough, (2016).

The study by Stambough (2016) investigated the amount of SSIs of a decolonisation protocol in which mupirocin and chlorhexidine were applied to all, compared to the application to S. aureus carriers only. All patients who underwent elective primary hip or knee arthroplasty between March 1, 2011 and March 31, 2013 (n = 1,864) were included in the control group and in case of surgery between July 1, 2013 and July 31, 2015 (n = 2,049) in the intervention group. Patients in the control group were screened and mupirocin and chlorhexidine were given to *S. aureus* carriers only. In the intervention group, mupirocin and chlorhexidine were applied to all patients. Mupirocin was given for five days, including day of surgery. The use of chlorhexidine varied between the two groups: patients in the control group used day of surgery wipes, and patients in the intervention group used twice daily chlorhexidine baths for five days. Patients were followed for 90 days to detect deep SSI and PJI, which were classified according to the National Healthcare Safety Network guidelines. In most patients, IV cefazolin was given as antibiotic prophylaxis and in case of allergy to penicillin, IV vancomycin and IV aztreonam

were given. Patients who resided in a nursing facility, were on dialysis, had been hospitalised within the past year, or had a documented history of MRSA infection, were administered IV vancomycin in addition to cefazolin Stambough, (2016).

Category 3
In one study, the differences in number of revisions due to SSIs in patients who had undergone a total joint arthroplasty was compared between a group that had been screened and had received mupirocin and chlorhexidine on indication, to a group in which chlorhexidine was applied only Malcolm, (2016).

The retrospective clinical cohort study by Malcolm (2016) compared the risk of revision after total joint arthroplasty between a group of patients who had been screened and treated according to a decolonisation protocol (intervention group) and a group of patients who had not been screened and had received chlorhexidine (control group). No reason was given as to why these patients had not been screened. The reported outcome measure was revision arthroplasty after THA or total knee arthroplasty (TKA). Revision was only assessed in patients with at least one year of follow-up. The criteria for revision surgery were not given Malcolm, (2016).
In the intervention group, carriers of *S. aureus* had received topical mupirocin for three days twice daily. All patients (both intervention and control groups) had used chlorhexidine body wipes pre-operatively and had received intravenous cefazolin as peri-operative antibiotic prophylaxis, or in case of MRSA carriage vancomycin. In total, 5678 patients were included in the study, of which 4042 (screened = 2291; not-screened = 1751) had at least one year of follow-up and were included in the analysis to report the number of revisions. The patients who had been screened (n = 2291; THA = 939; TKA = 1352), were compared to ones who had not been screened (n = 1751; THA = 700; TKA = 1051). The 1636 patients excluded from the analysis, were included in the study less than one year before the end of the study. Of the screened patients, twenty percent were colonised with MSSA and five percent were colonised with MRSA. At baseline, the intervention and control group were only different in Charlson Comorbidity index (CCI) score (p-value <0.01) Malcolm, (2016).

Results
Surgical site infections (SSIs)
Category 1 *(number of SSIs after screening and application of mupirocin and chlorhexidine on indication compared to a (historical) control group with unknown history regarding mupirocin and/or chlorhexidine)*

In the study by Baratz (2015), no statistically significant difference was found in SSIs between the group of patients who received mupirocin and chlorhexidine on indication (intervention group) and the historical control cohort (Relative Risk: 0.74, CI: 0.44 to 1.22, p-value = 0.28). This remains with stratification of patients based on primary (Relative Risk: 0.77, CI: 0.40 to 1.49, p-value = 0.51) and revision cases (Relative Risk:0.76, CI: 0.34 to 1.7, p-value = 0.65). All SSIs required surgical intervention. There were no statistically significant differences between the intervention and historical control group in the organisms causing the infections: MSSA (Relative Risk: 0.75, 0.23 to 2.45, p-value = 0.66), MRSA (RR: 0.48, CI: 0.20 to 1.13, p-value = 0.10) and total *S. aureus* (Relative Risk :0.56, CI: 0.28 to 1.11, p-value = 0.11). All identified infections required surgical intervention (intervention group, n = 27; control group, n = 33) Baratz, (2015).

In the study by Rao (2010) the infection rate in all patients, decreased from 2.7% in the pre-intervention control group to 1.2% in the group of patients who received mupirocin and chlorhexidine on indication (intervention group) (P = 0.009; OR 2.32 (95% CI 1.21 to 4.46). Eleven superficial (MRSA = 3; MSSA = 3; others = 5) and nine deep infections (MRSA = 5; others = 4) were found in the pre-intervention control group. Nine superficial (MSSA = 3; others = 6) and eight deep infections (MRSA = 2; others = 6) were found in the intervention group Rao, (2010).

In the study by Schweizer (2015) the rate of complex SSIs was lower in the group of patients who received mupirocin and chlorhexidine on indication (intervention group) compared to the historical control group (Rate Ratio = 0.48; 95% CI 0.29 to 0.80; p-value = 0.005). After stratification for type of surgery the mean rate was significantly lower in the intervention group compared to the historical control group in patients who underwent elective surgery (Rate Ratio = 0.51; 95%CI: 0.30 to 0.85; p-value = 0.009), but not in patients who underwent urgent surgery (Rate Ratio: 0.44; 95%CI: 0.07 to 2.72; p-value = 0.38) Schweizer, (2015).

In the study by Sporer (2016), the SSI rates were lower in the group of patients who received mupirocin and chlorhexidine on indication (intervention group) compared (2009: 0.20%; 2010: 0.59%; 2011: 0.32%; 2012: 0.53%; 2013: 0.23%; 2014: 0.12%) to the historical control group (1.11%) in patients who underwent THA or TKA. In patients who underwent primary THA, the SSI rates were lower in the intervention group (2009: 0.36%; 2010: 1.02%; 2011: 0.37%; 2012: 0.48%; 2013: 0.30%, 2014: 0.16%) compared to the historical control group (1.54%). The proportion of *S. aureus* SSIs was 66.7% in the control group and 33.3% in the intervention group (p-value > 0.05) Sporer, (2016).

Grading the evidence
The level of evidence was initially graded as low, because the data used was derived from three observational studies and one quasi-experimental study. Downgrading by at least one level was necessary because of limitations in the study designs: eligibility criteria, (loss to) follow-up and outcome assessment were not always clearly specified. Moreover, most studies did not adjust for confounders. Besides, the indication for screening was not always given in the study protocol, resulting in possible selection bias. Screening also led to a more appropriate antibiotic prophylaxis in the intervention group. In addition, there was inconsistency (probably due to heterogeneity in the protocols), indirectness (some outcomes assessed for patients who underwent total joint arthroplasty instead of THA) and imprecision (fewer outcomes noticed)

Category 2 *(number of SSIs after screening and application of mupirocin and chlorhexidine to all, compared to application on indication)*

In the study by Stambough (2016), the amount of SSI was significantly higher in the group of patients who received mupirocin and chlorhexidine on indication (control group) (n =15; 0.8%) compared to the group in which all patients received mupirocin and chlorhexidine (intervention group) (n = 5; 0.2%) in patients who underwent total joint arthroplasty (p-value = 0.013). This difference was also significant in patients who underwent THA (control n = 9 (0.8%); intervention n = 2 (0.2%); p-value = 0.03) Stambough, (2016).

Grading the evidence

The quality of evidence was initially graded as low, because the data used was derived from one observational study. Downgrading by at least one level was necessary as there were limitations in the study designs (no adjustments for confounders).

Category 3 *(number of revisions due to SSIs after screening and application of mupirocin and chlorhexidine on indication, compared to application of chlorhexidine only)*

The study by Malcolm (2016) indicated no differences in rates of revision arthroplasty between patients who received mupirocin and chlorhexidine on indication (intervention group) (n = 22 (1%)) and patients who received no mupirocin (application of chlorhexidine only) (control group) (n = 25 (1.4%)) (p-value = 0.17). There was a significant difference in the reason for revision. The incidence of revision due to prosthetic joint infection was significantly lower in the intervention group (n = 9 (0.4%)) compared to the control group (n = 16 (0.9%)) (p-value = 0.04). Of the nine patients who underwent revision because of prosthetic joint infections, one person was a carrier of MSSA and eight were non-carriers Malcolm, (2016).

Grading the evidence
The evidence was initially graded as low, because the data used was derived from one observational study. Downgrading by at least one level was necessary as there were limitations in the study designs: eligibility criteria, (loss to) follow-up and outcome assessment were not clearly specified. There was also some indirectness, because the outcome was assessed for patients who underwent total joint arthroplasty instead of THA.

Zoeken en selecteren

There was no study available in which the effects of the application of mupirocin and chlorhexidine either to all patients, or to *S. aureus* carriers only were compared to no application. Therefore, a new question was formulated to investigate the effect of screening and in case positive, application of mupirocin and chlorhexidine, compared to no screening protocol.

PICO-1: What are the effects of (*S. aureus*) screening and application of mupirocin and chlorhexidine, compared to no screening, in patients who underwent total joint arthroplasty?

P: (patients) patients who underwent total joint arthroplasty;
I: (intervention) screening and (in case positive for *S. aureus*) application of mupirocin and chlorhexidine;
C: (comparison) no screening;
O: (outcome) surgical site infection, revision.

The working group did not define outcomes a priori, but used definitions as provided in the studies.

Search and selection (Methods)
A literature search with relevant search terms was performed in the databases Medline (via OVID) and Embase (via Embase.com) on June 14 2017. The search strategy is provided in the tab “Verantwoording”. The literature search resulted in 138 hits. Studies about the (un)favourable effects of entering a screening protocol and pre-operative decolonisation according to a decolonisation protocol (in case positive for *S. aureus* application of mupirocin and chlorhexidine), compared to no screening protocol, in patients who underwent total joint

arthroplasty were selected. The studies that were found investigated the (un)favourable effects of mupirocin and chlorhexidine within a protocol, in which antibiotic prophylaxis was also given to the patients. Therefore, it is not clear whether the results are solely related to mupirocin and chlorhexidine, or to the adapted systemic prophylaxes in case MRSA was found. The studies show the effects of entering a screening protocol on different outcomes. Based on title and abstract 17 studies were pre-selected. After obtaining full text, eleven studies were excluded, and six studies were included in literature analysis (see exclusion table).

Verantwoording

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Laatst geautoriseerd : 12-02-2019

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

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Postoperatieve zorg bij een totale heup prothese (THP)

Deze module is onderverdeeld in twee submodules waarin de volgende uitgangsvragen worden behandeld:

1. Wat is het optimale interval van routinematige follow-up na een totale arthroplastiek en welke rol speelt beeldvorming hierbij?
2. Is antibioticaprofylaxe geïndiceerd bij patiënten met een gewrichtsprothese die een tandheelkundige ingreep ondergaan.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Routinematige follow-up bij een totale heup prothese (THP)

Uitgangsvraag

Wat is het optimale interval van routinematige follow-up na een totale arthroplastiek en welke rol speelt beeldvorming hierbij?

Aanbeveling

Routinematige follow-up van patiënten moet in ieder geval plaatsvinden zes tot twaalf weken, een jaar, en na tenminste vijf jaar na een totale heupvervanging, of eerder als de operateur daar aanleiding toe ziet.

Op basis van de recente literatuur is het niet mogelijk om een optimale frequentie van follow-up aan te geven na het vijfde jaar.

Röntgenonderzoek dient onderdeel te zijn van routinematige follow-up.

Overwegingen

Monitoring of patients shortly (6 to 12 weeks) after the operation concentrates on healing of the wound and on recovery of function. Broadly speaking, this stage is complete one year after surgery, including the fixation of an uncemented prosthesis. After the first year, routine follow-up is aimed at detection of complications such as polyethylene wear or osteolysis and at deterioration of function.

Lovelock and Broughton (2018) (expert opinion) discussed the need for routine follow-up after arthroplasty of the hip and knee. They stated that the early failure of the THA (within five years) is decreased because of the diminishing incidence of dislocation due to the increased use of the 32 mm head size and the use of components rated as Orthopaedic Data Evaluation Panel (ODEP) 10A. Nevertheless, they recommend to offer routine follow-up depending on age of the patient and type of prosthesis Broughton, (2018).

Polythylene particles could lead to osteolysis and subsequent loosening. When detecting this loosening on X-rays, an operative intervention should be advised. Loosening of components usually leads to complaints, although a few patients remain asymptomatic. Sandgren (2014) studied a cohort of 206 asymptomatic patients with several uncemented cup prostheses with a median follow-up of 10 years after surgery (range 7 to 14 years). They analysed peri-acetabular osteolysis using CT examinations. They found that 57 patients (27.7%) had peri-acetabular osteolysis of more than 10 mm. Wear was associated with osteolysis. Sandgren (2014) advised follow-up on a regular basis with CT scan. However, mostly these adverse reactions do not occur within the first 5 to 10 years after surgery. Therefore, it is questionable whether routine follow-up of many patients for a long time, with high radiation levels of the CT scan, to detect only a few patients with asymptomatic osteolysis or loosening is justified.

However, absence of any routine follow-up might lead to undetected silent osteolysis or loss of function, which may increase risk of falling with possibly devastating consequences.

If routine follow-up is considered, the following aspects might play a role in determining the optimal frequency:

- Risk of complications: risk is low in the first 5-10 years after surgery.
- Age of the patient at surgery: with a 10-year survival of 95% for a prosthesis, it is not necessary to routinely follow-up patients aged 70 years or older. These patients should be advised to return when they have complaints.
- Type of prosthesis.
- Not all patients will spontaneously contact their doctor. They should be reminded. By being followed up every 1, 2, or 3 years, patients get used to regular follow-up at a later stage, especially younger patients.
- Quality control: it is important for an orthopaedic surgeon to know the results of his/her own work. This is only possible by regular clinical and radiological monitoring of his or her own patients.

The working group recommends performing routine follow-up on patients six to twelve weeks, one year and at least five years after THA. Asymptomatic patients do not need routine follow-up within the first five years after surgery. Radiographic imaging should at least be done during routine follow-up. If wear is detected on X-ray during follow-up, a CT-scan may be considered.

Inleiding

After a successful total hip arthroplasty (THA), the question is whether routine clinical and radiological examinations are indicated. At the moment routine clinical and radiological examinations are advised six to twelve weeks, one year and five years after THA.

Conclusies

Very low GRADE	There seems to be no benefit of routine follow-up in asymptomatic patients within 5 years after total hip arthroplasty. *Sources (Christensen, 2013; King, 2004; Röder, 2003)*

Samenvatting literatuur

Description of studies and results
One new study was included Christensen, (2013). Also, two studies are described that were also included in the 2010 guideline (King, 2004 and Röder, 2003).

Christensen (2013) used a retrospective chart review of 249 patients after uncomplicated cementless primary THA, to study consequences of radiographic follow-up after three months and after twelve months. The radiographic examination had direct consequences in five cases (1.2%) out of 417 outpatient visits. However, in only two cases did the radiographs result in consequences other than increased follow-up Christensen, (2013).

Röder (2003) analysed the follow-up of 18,486 patients with a THA between 1967 and 2001 (18,486 THAs). Sensitivity, specificity, negative and positive predictive values with respect to acetabular and femoral loosening were evaluated for ten clinical variables: five different locations of pain (hip, buttock, groin, thigh, knee), four elements of pain on testing (over trochanter, on axial compression, internal rotation and external rotation) and

range of flexion. Sensitivities were all low (between 0.0 and 0.6), specificity values were all between 0.89 and 1.0. Positive predictive values increased from 0.00 to 0.66 in the ten years after surgery, negative predictive values decreased from 1.00 to 0.86. The authors concluded that routine follow-up of asymptomatic patients with THA was not necessary during the first five or six years Röder, (2003).

King (2004) found no difference in clinical outcome between 30 patients who had not shown up for follow-up between 6 months and 5 years following surgery, compared to 131 patients that had routine postoperative controls.

Grading of evidence
The quality of evidence started as low as only observational studies were included and was downgraded one level to very low because studies with other time frames were used (indirectness).

Zoeken en selecteren

To answer the question a systematic literature analysis was performed for the following research question: What are the (un)favourable effects of routine follow-up in patients that underwent a total hip arthroplasty?

P: patients that underwent a total hip arthroplasty;
I: follow-up
C: -
O: -

The working group did not define outcomes a priori, but used definitions as provided in the studies.

Search and select (Method)
A literature search was performed with relevant search terms on 18 May 2017 in the database (Medline (via OVID). The search strategy is provided in the tab "Methods". The literature search resulted in 197 hits. Studies were selected using the following selection criteria: effects of follow-up in patients who underwent a total hip arthroplasty. Studies comparing two different types of follow-up were not selected (for example web-based compared to in-person). Based on title and abstract eight studies were pre-selected. After obtaining full text, one new studies was included in literature analysis. Two studies of the 2010 guideline fulfilled the PICO and were also included in the literature summary. No studies were found evaluating the kind of radiographic imaging necessary for routine follow-up after a THA.

The most important study characteristics are described in evidence tables.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

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Hematogene besmetting bij een totale heup prothese (THP)

The working group refers to the module 'Antiboticaprofylaxe bij tandheelkundige ingrepen bij patiënten met een gewrichtsprothese' Guideline 'Antibioticaprofylaxe bij gewrichtsprothese') for recommendations about the indication of antibiotic prophylaxis in patients having a hip prosthesis who underwent a dental procedure : https://richtlijnendatabase.nl/richtlijn/antibioticaprofylaxe_bij_gewrichtsprothese/antibioticaprofylaxe_bij_gewricl

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Pre- and postoperatieve fysiotherapie bij een totale heup prothese (THP)

Zie voor de complete richtlijn van het KNGF:
https://www.kngf.nl/kennisplatform/richtlijnen/artrose-heup-knie

Deze module is onderverdeeld in twee submodules waarin de volgende uitgangsvragen worden behandeld:

1. Pre-operatieve fysiotherapie
2. Post-operatieve fysiotherapie

Verantwoording

Laatst beoordeeld : 12-02-2019
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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Pre-operatieve fysiotherapie bij een totale heup prothese (THP)

Zie: KNGF-richtlijn Artrose heup-knie, Praktijkrichtlijn, Therapeutisch proces, C.2.2, pagina 12

Aanbevelingen

Overweeg om patiënten met een verhoogd risico op vertraagd herstel te verwijzen naar pre-operatieve oefentherapie, bestaande uit spierkrachttraining, aerobe training en functionele training.

Overweeg om patiënten zonder verhoogd risico op vertraagd herstel te verwijzen naar pre-operatieve oefentherapie welke beperkt is tot het aanleren (en monitoren op de uitvoering) van oefeningen die de patiënt zelfstandig uitvoert. Leer tevens alle patiënten een loophulpmiddel te gebruiken indien dat nodig is tijdens de postoperatieve fase.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Post-operatieve fysiotherapie bij een totale heup prothese (THP)

Zie: KNGF-richtlijn Artrose heup-knie, Praktijkrichtlijn, Therapeutisch proces, C.2.3, pagina 12

Aanbevelingen

Verwijs patiënten met een verhoogd risico op vertraagd herstel en/of postoperatieve complicaties bij voorkeur naar postoperatieve oefentherapie, bestaande uit spierkrachttraining, aerobe training en functionele training.

Overweeg om patiënten zonder verhoogd risico op vertraagd herstel en/of zonder postoperatieve complicaties te verwijzen naar oefentherapie welke beperkt is tot het aanleren (en monitoren op de uitvoering) van oefeningen die de patiënt zelfstandig uitvoert.

Verantwoording

Laatst beoordeeld : 12-02-2019
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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Organisatie van fast-track-behandeling bij een totale heup prothese (THP)

Uitgangsvraag

Wanneer is er een indicatie voor fast-track-behandeling en aan welke voorwaarden moet de organisatie voldoen?

Aanbeveling

Een fast-trackprogramma heeft de voorkeur na een totale heupprothese, onder voorwaarde dat er een protocol is waarin is opgenomen:

- goede voorlichting;
- opioïdsparend protocol voor anesthesie en pijbestrijding;
- maatregelen om bloedverlies te beperken (tranexaminezuur);
- mobilisering op de dag van de operatie;
- gestandaardiseerde ontslagcriteria (waarin opgenomen ADL);
- en desgewenst een individueel revalidatietraject.

Een fast-track programma dient rekening te houden met fragiele patiënten onder het motto “first better – then faster”.

Overwegingen

Outpatient surgery
The high-volume centre RCT by Goyal, (2017) evaluated 220 patients who had total hip arthroplasty (THA) surgery between July 2014 and September 2015. Patients were randomised between outpatient surgery (discharge planned on the same day as surgery) and inpatient surgery (discharge planned after an overnight stay). Primary endpoints were postoperative pain, peri-operative complications and healthcare provider visits (re-admission A&E or physician’s office) and relative work effort for the surgeon’s office staff. There was no significant difference in pain on the day of surgery and after 4 weeks, but on the first day after surgery outpatients reported more pain than inpatients. After 4 weeks, Harris Hip Scores showed no difference between the two groups. Of the 112 patients randomised to outpatient surgery, 85 (76%) were discharged as planned. Of the remaining 27 patients, 26 were discharged after one night in the hospital and one was discharged after two nights. Of the 108 patients randomised to inpatient surgery, 81 (75%) were discharged as planned. There was no difference in the number of re-operations, hospital re-admissions without re-operation, A&E visits without hospital re-admission, or acute office visits. Goyal (2017) concludes that outpatient THA can be implemented in a defined patient population. Because 24% (27 of 112) of patients planning to have outpatient surgery could not be discharged on the same day, facilities to accommodate an overnight stay should be available Goyal, (2017).

The prospective two-centre cohort study of Gromov (2017) reports on the feasibility of outpatient THA (and total knee arthroplasty (TKA)) in unselected (consecutive patients referred to orthopaedic surgeons in a hospital for THP without any selection) patients. Of the 557 patients, 304 were THA and 253 were TKA. Of the 304 THA

patients who were referred to the participating surgeons during the study period, 55% were potentially eligible for outpatient surgery. 34 patients were excluded for the reason of living alone. Of the remaining 133 patients, 47 (35%) were discharged on the actual day of surgery Gromov, (2017).

Fast track

Jørgensen (2017) describe the results of a prospective observational study in 13,775 consecutive THA (N=6553) and TKA (N=7222) patients with similar fast-track protocols and a median length of stay of 2 days. Of a total of 44 deaths (30 THA/ 14 TKA) (0.3%), 28 (20 THA/ 8 TKA) (0.2%) were found to have a certain or probable relation with surgery and were considered as surgery-related. Surgery-related deaths were more common after THA than TKA (0.3% versus 0.1% P = 0.044), occurred after median 14 days and 19 of 28 were between day 0 to 30. The most common initial organ dysfunction for surgery-related deaths was pulmonary (6/28) and gastro-intestinal (6/28), while the most commonly reported causes of death were pulmonary (9/28) and cardiac events (6/28) Jørgensen (2017).

Thrombo-embolic events (TEE) are serious complications after total hip (THA) and knee arthroplasty (TKA), with reported in-hospital incidences of about 0.5 to 1% for venous thrombo-embolic events (VTE) and 0.2% for myocardial infarctions (MI) and stroke with a traditional protocol Jørgensen, (2017).

Jørgensen (2016) describe the results of a prospective observational study in 13,775 consecutive THA/TKAs with similar fast-track protocols and a median length of stay (LOS) of two days. "Early" TEEs (within one week of surgery) consisted of 9 (0.07%) MI, 10 (0.08%) strokes, 13 (0.09%) pulmonary embolisms and 11 (0.08%) deep venous thromboses. Jørgensen conclude that the incidence of "early" TEEs after fast-track THA and TKA is low. Improving peri-operative treatment of anaemia may further reduce the number of MIs Jørgensen (2016).

Khan (2014) compared two consecutive unselected cohorts of 1,369 THA patients and 1,631 TKA patients with a traditional protocol (2004 to 2008) with 1,256 THAs and 1,744 TKAs with an enhanced recovery protocol (2008 to 2011). The median LOS in the enhanced recovery group was reduced (3 days versus 6 days; p = 0.01). Blood transfusion rate was also reduced (7.6% versus 23%; p <0.001), as was return to theatre rate (p = 0.05). Myocardial infarction at 30 days (0.4 versus 0.9%, p=0.03) and mortality at 30 days (0.2 versus 0.5%, p=0.03) was lower in the enhanced recovery group, mortality at 90 days was not significantly different (0.5 versus 0.8%, p=0.1). Other outcomes showed no significant difference. Khan (2014) conclude that the enhanced recovery programme has achieved a statistically significant reduction in LOS and in cardiac ischaemic events for patients, with a near-significant decrease in return to theatre and in mortality rates.

Summarizing

The narrative review by Hansen (2017) summarises literature and provides insights into fast track surgery in THA. Fast track surgery in THA resulted in a reduction in postoperative LOS, shorter convalescence and rapid functional recovery without increased morbidity and mortality. According to Hansen, fast-track THA surgery now works extremely well in the standard THA patient. However, all patients are different and fine-tuning of the multiple areas in fast-track pathways to get patients with special needs or high co-morbidity burden through a safe and effective fast-track THA pathway is important. Hansen provides an overview of possible pre-operative and peri-operative optimisations. These include patient information and teaching, an opioid-sparing pain and anaesthetic protocol and mobilisation on the day of surgery.

Another narrative review by Galbraith (2018) concluded that pre-operative education programmes, outpatient consultation, pre-anaesthetic assessment, pre-procedural physiotherapy, day-of-surgery admission, pre-operative medications, type of anaesthesia, blood loss reduction protocols, multimodal analgesia delivery, day-of-surgery mobilisation, thrombo-embolic prophylaxis and ongoing rehabilitation are essential in enhanced recovery. Galbraith also concluded that that the impact of individual variables requires further research.

Until recently, the reports of outpatient THA have been anecdotal, single surgeon or single institution based or with selected patient populations. However, two more recent papers by Goyal et al. (2017) and Gromov et al. (2017) report respectively on a multi-centre randomised trial and a multi-centre study with unselected patients (Goyal, 2017; Gromov, 2017). Both studies confirmed the feasibility of outpatient THA, although many challenges need to be overcome before it can be defined as an established treatment option and more widespread use recommended.

The published studies on outpatient THA from Europe have all been from institutions that have a well-established fast-track protocol. As a result of their programmes, these hospitals have seen their length of stay gradually decrease to a point where outpatient THA is feasible. For most hospitals, outpatient THA surgery should not be a goal in itself, but should rather be the result of a successful, already implemented fast-track programme based on the concept “first better – then faster.”

Inleiding

In the past decades, fast track programmes have successfully been introduced in orthopaedics. A combination of organisational and medical improvements in peri-operative protocols has led to an enhanced recovery of patients after total hip arthroplasty (THA), lowering morbidity and mortality.

Zoeken en selecteren

No systematic literature review was performed for this question. The recommendations are based on an exploratory search and the expert opinion of the working group.

Verantwoording

Laatst beoordeeld : 12-02-2019
Laatst geautoriseerd : 12-02-2019

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Organisatie van zorg bij kwetsbare ouderen met een totale heup prothese (THP)

Uitgangsvraag

Hoe moet de zorg georganiseerd worden voor kwetsbare ouderen die een totale heupprothese ondergaan?

Aanbeveling

Screen alle patiënten van 70 jaar en ouder op kwetsbaarheid met behulp van een gevalideerd instrument (bijvoorbeeld de VMS-screeningsbundel).

Laat patiënten die positief screenen op kwetsbaarheid preoperatief beoordelen door middel van een comprehensive geriatric assessment door een medical specialist met expertise op het gebied van geriatrie.

Overwegingen

In addition to the choice of treatment, there are other important aspects that play a part in the performance of treatment of vulnerable elderly people. This concerns the concept of frailty. This is a condition associated with an increased risk of loss of function and which is distinguished from aging, constraints and multi-morbidity (NVKG, 2010).

The geriatric patient distinguishes himself from other patients through (NVKG, 2010):

- a (greater risk of) frailty or "the uncertain physical, psychological and social equilibrium";
- usually a higher age;
- Illnesses and / or handicaps associated with high age;
- the inter-acting multi-morbidity;
- the bigger (inter-)individual variability;
- they often prefer improvement of self-reliance, mobility and quality of life instead of extension of life.

So, in the category of patients with osteoarthritis of the hip there must be specific attention for:

- functioning in general and self-reliance;
- complications or diseases, which present themselves through geriatric syndromes (delirium, falling);
- a decreased amount of social support;
- a decreased awareness of problems by the patient due to cognitive impairment or visual impairment during the treatment;
- polypharmacy.

In summary, it is important – in addition to the orthopaedic problem - to judge the extent of vulnerability of the person in question. The complexity of co-morbidity, polypharmacy and cognitive disturbances emphasises the importance of co-operation between the orthopaedic surgeons and geriatricians when setting the operation indication (or rejecting it). This can be done by selecting specific patient categories for more intensive peri-operative guidance by a geriatric team or a generalistic medical specialist with experience in elderly care.

The Comprehensive Geriatric Assessment (CGA) should be used to judge the frailty of a patient. Tools for screening might possibly give an indication of vulnerability, but are unable to screen adequately and give a competent advice. The CGA is an extensive clinical geriatric examination, defined as a "multidisciplinary research that identifies and explains the multiple problems of an elderly as much as possible, examines a patient's abilities and needs, in order to achieve a coordinated and comprehensive care plan for the individual". A CGA has an added value with regard to vulnerable older people, especially in the areas of survival, quality of life, self-reliance and institutionalisation.

Screening lists are available for the various domains within the CGA. Some of these lists screen for vulnerability or risk of functional decline (i.e. the ISAR-HP), others focus more on geriatric syndromes, such as a delirium risk assessment or the Patient Safety Management System ("Veiligheidsmanagementsysteem") criteria (VMS-criteria screening bundle). The latter looks at four domains: delirium, risk of falling, malnutrition and functionality.

A CGA is not required for every elderly patient. It is advised to initially perform a screening for vulnerability in patients 70 years and older. Almost all hospitals in the Netherlands have implemented the screening according to the VMS criteria screening bundle. This screening is preferably done when the indication for hip arthroplasty therapy is set and can be performed during pre-operative screening (POS) in an outpatient clinic setting (NVKG, 2013; Partridge, 2014).

It is of great importance that screening for frailty takes places systematically. Additionally, on indication, judgement by a geriatrician should be performed. In case of positive screening, it is useful to refer the patient pre-operatively to the outpatient clinic for further assessment by a CGA. Based on the outcome of the CGA, a programme can be drawn up. Pre-operative and peri-operative recommendations (id est prevention of delirium) can be given and advice about the care after the hospital admission. In the case of frail elderly people with a high risk of (geriatric) complications, structural co-treatment between the orthopaedic surgeon and the geriatrician should be considered. Then, the geriatrician is jointly responsible for ensuring that good protocols are in place to use geriatric expertise.

In short, the orthopaedic surgeon sets the indication for the treatment, the anaesthesiologist assesses the operation risk and the clinical geriatrician maps the vulnerability and co-morbidity. In the majority of patients, the attention of the orthopaedic surgeon and the anaesthesiologist before an operation is sufficient. All persons 70 years and older should be screened. In case of positive screening (id est: increased vulnerability, possibly frailty) there is an indication for additional screening according to a comprehensive geriatric assessment to map frailty, co-morbidity and possible contra-indications and give advice leading to a better outcome.

Inleiding

In the next decades, the total number of elderly people in society will increase, as well as the life-expectancy, leading to more and more of the "oldest old". Elderly people are more active than they used to be in the past and will probably ask for hip arthroplasty at more advanced ages. A substantial part of the patients above the age of 70 years will be "frail" (due to co-morbidity, polypharmacy and cognitive disturbances) so specific considerations have to be taken into account on the one hand to avoid the need for joint arthroplasty surgery and on the other hand, when this is indicated to minimise the length of stay in the hospital, to reduce the risk of

complications and minimise the functional decline and the duration of rehabilitation.

In addition to the joint problems, elderly people often have additional diseases, id est diabetes and cardiovascular diseases. Nearly 70% of the Dutch elderly aged from 65 to 79 years have serious, life-shortening co-morbidities when they attend the out-patient clinic. Above the age of 80 years this figure rises to almost 80% Piccirillo, (2008). Co-morbidity influences the chance of success of an operation, the length of stay in the hospital and the duration of the period of rehabilitation. Patients with cognitive disturbances and/or sensory deprivation have a greater chance of serious delirious episodes postoperatively. The presence and extent of co-morbidity can thus influence the choice of treatment and therefore personalised care adjusted to the frail elderly is needed.

Frailty increases with age: in the age group of 65 to 69 years about 4% can be considered frail; 7% from 70 to 74 years of age; 9% from 75 to 79 years of age; 16% from 80 to 84 years of age; and 26% above the age of 85 years Clegg, (2013). In the year 2010, it was estimated that there were around 690,000 frail persons in the age range of 65 years and older in the Netherlands and - based on a demographic estimation - the number of frail elderly will increase by another 470,000 people to a total of 1,160,000 persons in the year 2030 van Campen, (2011).

Zoeken en selecteren

No systematic literature review was performed for this question.

Verantwoording

Laatst beoordeeld : 12-02-2019
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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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