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Do forced air patient-warming devices disrupt unidirectional downward airflow?

Legg AJ, Cannon T, Hamer AJ.

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Reviewers: Hideki Nagata & Reda Ramadan

INTRODUCTION

Infection in joint arthroplasty in the lower limb is currently approximately <1%. A number of previous studies have shown that this is due to a combination of ultra-clean unidirectional airflow, patient warming, IV antibiotics, sterile occlusive theatre clothing or total body exhaust systems.

Studies have shown that ultra clean air reduces the rate of bacterial contamination of the wound and that vertical unidirectional airflow ventilation is more effective than horizontal and with the use of Howorth enclosure extensions.

Patient warming has been shown to reduce the surgical site infection but also cardiovascular events, perioperative pain, bleeding and decrease length of hospital stay. Traditionally, this has been done by forced-air warming. Concern exists about disruption to the uni-directional flow and the potential to increase pathogenic organisms.

METHODS

Originality

A previous study has indicated that with forced air devices that there is no increased bacterial level in the operating. The authors state that to date, there is no literature showing that forced air warming devices disrupt laminar flow.

Ethics

There was no mention of ethical approval for the study. However, this was an observational study with volunteers with no potential risk.

Aims and hypothesis

The null hypothesis was that forced air and radiant devices do not increase the number of particles or affect the temperature at the site of the operation when compared with no warming device.

Study type / level of evidence

Case-control study – Level of Evidence Type 3

Study design

Two devices (forced air device and radiant warming blanket) and a control were tested on volunteer. The theatre setup involved the volunteer in supine position, draped for a TKR within a Howorth enclosure that had been validated. The surgeon wore sterile clothing, theatre hood and body exhaust. There was no theatre nurse, assistant or trays. No tourniquet was applied on the volunteer. The lights were raised as high as possible to reduce disruption to the airflow surgical site temperature.

Temperature measurements were taken 10 cm above the surgical site, before and after 30 minutes of inflating the forced-air device. A probe was used and the rise in temp was calculated. A control

measurement was taken outside the Howarth enclosure and the process was repeated 5 times for each device.

Particles were measured similarly using a handheld counter measuring three particle sizes (0.3, 0.5 and 5.0).

Statistics

Two-tailed t-tests used for all data although an unpaired t-test appears to have been used for calculating the temperature statistical significance. These tests appropriate for this group. $P < 0.05$ statistically significant is an appropriate measure.

RESULTS

Analysis

There was a statistically significant rise in temperature over the surgical site with the use of the forced-air device when compared to the radiant blanket and control ($p < 0.0001$). The number of mean particles over the surgical site also increased significantly with the forced-air device compared to the radiant blanket and control for all particle sizes.

Accuracy and clarity of presentation

Tables are clear to interpret and there is completeness of data.

CONCLUSION

The authors state that in their experimental set-up theatre, forced-air warming devices significantly increase the number of airborne particles over the surgical site and increase surface temperature, and therefore reject their null hypothesis. They are quick to mention that from this study, it is not possible to conclude that this difference would actually lead to any increase in surgical site infection and that although the numbers of particles are increased, whether this was transporting any bacteria.

Limitations

The numbers used for this study was very small with only 5 recordings for each device. Although, trying to minimise disruption to the unidirectional flow, the theatre set-up was not realistic for clinical practice. Surgical lights do most likely disrupt the unidirectional flow and can often be very warm. They may on their own affect the surgical site independently and the rise in particles and temperature caused by the forced-air device may not be significant. Tourniquets are almost universally used in total knee arthroplasty and it is in itself a forced-air device that may also influence the surgical field. 10cm above the surgical field has been chosen for the recordings to be made but we are unsure of the clinical relevance of this. Total knee arthroplasty usually takes on average longer than the 30 minutes used in the study and thus it is likely that both temperature and particle numbers would be greater with a prolonged period of study. The particle measuring device has not been validated and particle sizes measured have been arbitrary selected. What evidence exists that these particles are the sizes clinically relevant in carrying bacteria or even cause infection in joint arthroplasty?

Conclusions justified and relevance

The study is an interesting article and the authors are justified in their conclusion. However, we do not feel that it directly answers the question whether forced-air devices disrupts unidirectional air flow. They have shown it increases the number of particles and local surgical site temperature but hasn't shown how this affects the airflow. To do this, the study would need to visualise the airflow over the surgical site, which the authors in fact mention.

From a clinical point of view, this study has not shown whether forced-air devices actually increase surgical site infection. We are unable to confirm if the increased numbers of particles are actually carrying any pathogenic bacteria and whether temperature has any effect on the local airflow. Therefore, the clinical relevance of this study may not be that useful.

Sliding hip screw versus Targon PF nail in the treatment of trochanteric fractures of the hip: A randomised trial of 600 fractures

MJ Parker, TR Bowers, GA Pryor

J Bone Joint Surg [Br] 2012;94-B:391–7.

Reviewers: Josephine McEwan and George McKay**Introduction**

We were interested in reviewing this paper as standard practice in our trust is to use sliding hip screws for trochanteric hip fractures and cephalomedullary nails are infrequently used. We wanted to examine the most recent publication to assess whether or not there was a need for change in clinical practice. The paper is a randomised trial which aims to determine whether the sliding hip screw (SHS) or the Targon PF is a superior fixation for extracapsular proximal femoral fractures.

Methods

This was a prospective randomised trial over a seven year period of trochanteric hip fractures managed surgically that presented to a single institution. The patients were randomised to treatment with a SHS (n=300) or Targon PF (n=300) via a sealed envelope by an independent source. Exclusion criteria have been clearly stated and a patient flow diagram demonstrates the study numbers. Data was collected using a standardised form to document age, sex, mental health assessment, ASA grade and residential status. Mobility assessed by a validated scoring system. The fracture pattern was categorised into four groups: 1) basal two part fractures, 2) stable trochanteric, 3) unstable trochanteric and 4) transtrochanteric. All operations were undertaken or supervised by the lead clinician under fluoroscopic guidance. Intraoperative details such as length of anaesthesia, length of surgery, fluoroscopic screening time, open reduction of fracture, difficult proximal screw insertion, difficult locking screw, reaming of femur, requirement for blood transfusion and mean number of units of blood transfused. Post operatively all patients were mobilised fully weight bearing with no restrictions. They were reviewed 6 weeks post discharge and subsequently assessed at 3, 6, 9 and 12-months by telephone by a nurse blinded to surgical intervention. Assessment comprised of a pain score. Complications of fracture healing were recorded.

Statistics

Binary outcomes were analysed using Fisher's exact test, continuous data was analysed using unpaired t-test and the Mann-Whitney U test for non-parametric data, all with intention-to-treat basis. A power calculation is included and justification for the subsequent change in recruitment numbers.

Results

The statistically significant results for this trial were longer duration of surgery for the Targon PF (49 minutes vs 46 minutes for the SHS, $p < 0.001$) and increased fluoroscopic screening times for the Targon PF (0.5minutes vs 0.3minutes for the SHS, $p < 0.001$). There was no statistical significance for any other outcome including length of hospital stay, pain scoring, mobility or healing complications. However, the authors identified a trend towards improved mobility with the Targon PF. The conclusions drawn were that both implants yielded comparable results and the Targon PF tended to be more technically difficult to insert

Discussion**Strengths**

1. This is a prospective randomised trial representing level 1 evidence.
2. The cohorts contain a large number of patients.
3. Power calculation initially made.
4. Follow up assessment was additionally blinded.
5. The authors used validated scoring systems for subjective outcome measurements.
6. The same lead clinician performing/supervising surgery implies consistency in technique, however, there are potential confounding issues with the “single supervising surgeon” approach used by the authors. These are discussed in the section below.
7. Clear patient flow diagram.
8. Appropriate statistical analysis has been performed and the data clearly presented.
9. Only a small number of patients were lost to follow up.

Weaknesses

1. A large number of patients were omitted from the study due to the exclusion criteria, for example 48% of patients were excluded due to the lead clinician not being available at the time of surgery.
2. Not all the outcome measures in the results have been identified in the proposed methods
3. There was a change to the initial number of patients thought to be required for recruitment, but a new power calculation is not included.
4. It remains unclear who the operating surgeon was for each case. The lead clinician was reported to be present for all cases but it is not apparent whether he performed each operation or what degree of input he had. This may potentially have an impact on the outcome. For example, a nail may be classed as a more technically demanding procedure (indeed the paper alludes to this, with increased operative time and increased difficulty) and therefore the lead surgeon may have personally performed all such cases, whereas the sliding hip screw cases may have been performed by less experienced surgeons, with the lead clinician supervising scrubbed or unscrubbed. This may influence the results as the outcomes for each group may be less comparable, as the grade of surgeon may have had an impact on some key outcomes such as length of surgery and fluoroscopic screening time.

Summary

This study represents a useful contribution to the existing body of work on the debate between the use of sliding hip screws and intramedullary devices for the treatment of these fractures nails. This study supports the current practice in our hospital where sliding hip screws provide the mainstay of surgical treatment in this group, and does not support a change in practice currently.

Independent predictors of revision following metal-on-metal hip resurfacing: A retrospective cohort study using National Joint Registry data.

Jameson SS, Baker PN, Mason J, Porter ML, Deehan DJ, Reed MR
 J Bone Joint Surg [Br] 2012;94-B:746-54.

Reviewers: Greg Pickering and Vinod Sharma

Introduction

This paper was chosen as hip resurfacing and metal-on-metal implants as a whole remain contentious topics. Conflicting views from the literature with regards to hip resurfacing, and the ever unravelling debate on metal-on-metal prostheses mean that an on-going need for unifying data remains. This paper by Jameson et al is the largest series of data yet to be analysed on the topic of hip resurfacing.

Methods

This was a retrospective cohort study using data entered into the National Joint Registry (NJR) Database from 2003 until December 2010. Inclusion criteria were the use of primary hip resurfacing for a primary

diagnosis of osteoarthritis (OA). Clear exclusion criteria were listed and included performing THR using resurfacing components, dysplasia, bridging cups, and the use of the anterior approach for surgery. Following implementation of these criteria the data from 27971 cases was analysed.

A calculated 'survival time' to failure was recorded and a series of covariates were explored to calculate their associated risk for affecting this survival time. Undergoing a revision procedure was considered to be a failure event, and these events were identified from tied data within the NJR Database. Time between index procedure and revision procedure was used as a measurement of survival of the joint.

Statistical analysis was performed using Cox's proportional Hazard model. This model assumes that there is an underlying unspecified constant baseline hazard (i.e. given enough time all cases will proceed to failure), and that this can be influenced both positively and negatively by a series of external covariates.

Results

Of the 46,190 recorded procedures within the NJR database 27,971 procedures were eventually studied, representing data from 722 different consultants within 376 different surgical units. The majority (69.1%) of patients were male, and almost all had an ASA grade of ≤ 2 (97.1%). Mean age was 55 (53% of patients were aged 56 and over). The Birmingham Hip Resurfacing (BHR; Smith & Nephew, Memphis, Tennessee) was the most commonly used prosthesis in 55.3% of cases. A posterior approach was used in 71.7% of procedures. Consultants were listed as performing the procedure in 93% of cases

In total 1003 patients (3.59%) underwent a revision procedure. The most commonly listed reasons for this were aseptic loosening, peri-prosthetic fracture and pain without cause. Revision due to soft tissue metallosis was only 7.1%. The whole study population revision rate at 5 years was 4.76%

Statistically significant predictors of expeditious implant failure were female gender (HR 1.3), ASA ≥ 3 (HR 1.74), small femoral head size (<48mm) and procedure completed by a surgeon who had performed less than 50 of these operations during the data collection period (HR 1.36). Age, BMI, surgical approach and grade of surgeon did not significantly influence risk of revision. Analysis for brand identified all five alternatives to the BHR as having higher revision rates (HRs between 1.43 and 2.82). Tests for interaction between covariates were not statistically significant.

Sub-analysis for patients aged <60 years showed a revision rate of 6.05% at 5 years which can be compared to rates of 2.79% for Hybrid THR and 3.25% for cemented THR (NJR Data). Further sub-analysis of the BHR within this patient group yielded a revision rate of only 1.59%.

Discussion

Strengths

- This is the largest analysis of hip resurfacing data to date.
- The paper looked to answer a relevant study question.
(Although the use of resurfacing is decreasing - possibly due to metal-on-metal concerns)
- The study uses independently entered data from the NJR Database
- Clear acknowledgment of the limitations of the data by the authors.
- Relevant identification of covariate factors studied, e.g. sex, age, implant brand, etc.
- Well defined exclusion criteria.
- Good use of the BHR as a gold standard for comparison.
- Results presented as Hazard Ratios with 99% Confidence Intervals. Care taken to reduce type 1 error.
- Good discussion about various theories of failure within various groups.

Weaknesses

- This is a retrospective cohort study.
- Entry of data onto the NJR is voluntary; therefore the data is only as good as what's reported.

- All procedures with missing variables (incomplete forms) were excluded which may have affected the outcome.
- 36.5% of the initial study population were excluded following implementation of the exclusion criteria (43,329 procedures for primary OA , 27,973 procedures analysed)
- Procedures using an anterior approach were excluded. The documented reason for this was that this approach was used in less than 100 cases. This is a potential cause for exclusion of data from more experienced surgeons.
- Revision was taken as a surrogate marker of failure. No correlation of findings for patients living with pain and other comorbidities. This has been acknowledged by the authors.
- An endpoint for the study population of December 2010 means that not all patients in the study have reached the same time post primary procedure, nor does it account for patients awaiting revision surgery for whatever reason. This has been acknowledged by the authors.
- Despite the fact that more than one of these covariates must have been present within a number of cases analysed there was no significant increase in risk when viewed together.
- Data from procedures performed for other indications (e.g. traumatic OA) was excluded.
- The widely considered very important factor of implant position is not recorded in the NJR Database. This has been acknowledged by the authors.
- Different generations for each implant not considered individually, and benefits for latter generations may be lost amongst the greater hazard risks from earlier versions.
- The decision to rank surgeon volumes (low, medium, high) is arbitrary. Also low volume surgeons may have identified concerns earlier than their colleagues, discontinuing performing this procedure influencing the magnitude of negative outcomes encountered.
- The factors investigated have already been analysed in previous studies. This paper brings nothing new to the debate, only adding re-affirmation to results from previous studies.
- Unable to truly correlate the significance of metal debris as the cause for needing revision.

Conclusions

Hip resurfacing outcomes are independent of age, as well as BMI, approach and grade of surgeon. Female patients, those who require small components (<48mm) and surgeons performing low numbers (<50) of this procedure are associated with significantly increased rates of failure. There are considerable variations in the rates of failure between brands of resurfacing components with the BHR having the lowest rates of revision. Based on results for head size and the recommendation by authors for a lower ODEP rating for the <47 mm implants an operating surgeon must be ready to convert to an on table THR if the femoral head size measures <47 mm intra-operatively.

Discussion

Despite femoral neck fracture and reactions to metal debris being the most widely reported reasons for revision in the literature, aseptic loosening or lysis was the most common cause for revision in the data studied. Metallosis as indication for revision only accounted for 7.1% of cases in this study. An acknowledgement to the potential contribution of metal debris to this aseptic loosening is raised by the authors. We would suggest that these cases may need to be correlated with retrieval studies.

Overall we rate this paper as a good study, which re-affirms previously reported risks of performing hip resurfacing on females and of using small size components. This study provides information which can be used in the consultation and consent process enabling both surgeon and patient to reach an informed decision with regards to the operative planning process.

Combined (mechanical and pharmacological) modalities for the prevention of venous thromboembolism in joint replacement surgery

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J Bone Joint Surg [Br] 2012;94-B:729-34.

Reviewers: Abdullah Hanoun, Adekoyejo Odutola

INTRODUCTION:

This is a systematic review and meta-analysis, of all randomised controlled trials of combined intermittent mechanical compression and pharmacological intervention used to prevent Deep Vein Thrombosis (DVT) and pulmonary embolism (PE) in patients undergoing total knee replacement (TKR) and total hip replacement (THR).

AIMS:

To compare the efficacy of combined intermittent mechanical compression and pharmacological prophylaxis, against each method alone as prevention for DVT and PE after TKR or THR. DVT and PE were extracted as separate endpoints.

METHODS:

Electronic literature searches of MEDLINE and SCOPUS using the terms “mechanical or pneumatic compression” were performed. Additional studies were identified through the reference list of the trials found in the electronic search and further trials were found through manual searches of journals and conference proceedings.

Exclusion criteria were short-term use of the mechanical compression, non-concurrent use of the combined modalities, or the use of different agents in the two study groups.

Outcome measures: DVT and PE.

Statistical analysis: Separate analysis for PE and DVT and also for the type of surgery were performed.

Risk ratio was calculated and used for assessment of dichotomous outcomes using the Mantel-Haenszel method.

Chi-squared tests and inconsistency statistics were used to assess heterogeneity.

Numbers needed to treat were calculated for significant findings.

LEVEL OF EVIDENCE:

Level 1 (Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence)

SUMMARY OF PAPERS:

Six RCTs were found with total of 1399 patients.

The mean age of patients was 65.7 yrs.

Randomisation was done by a sealed envelope method in one study, the odd or even date of birth in a second study, and not mentioned in the rest.

Two studies had intermittent mechanical compression as the control group whilst the other four had pharmacological prophylaxis as the control group.

The treatment group in all the studies had a combination of mechanical and pharmacological prophylaxis.

DVT diagnosis was established with ultrasound in five trials and venography was used in two of them.

The tests of DVT were done at patient's discharge and up to day 12 postop.

Eight patients were excluded from one study for non-compliance, confinement to bed for more than one week, premature transfer to different institution, re-operation, or not having ultrasonography prior to discharge.

Five patients were excluded from another study as they missed their ultrasonography.

PE was diagnosed on scintigraphy or CT pulmonary angiogram.

Follow up was extended to three months in three studies to assess long-term efficacy.

In two studies, the radiologists reading the venograms or performing the ultrasounds were blinded to patient allocation.

RESULTS:

In total knee replacement (TKR):

Two trials compared the treatment group (combined modalities) with a control group consisting of anticoagulation alone for the prevention of PE, whilst three trials had the same comparison groups for DVT prevention.

There was a total of 1 PE event in the control group and 0 in the treatment group ($P=0.50$).

The incidence of DVT was 18.7% in the control group and 3.7% in the treatment group ($P=0.03$). The risk ratio for DVT was 0.27.

No trials had the treatment group compared with a control group of mechanical compression alone.

In the total hip replacement (THR):

Three trials had mechanical compression alone as the control group.

No PE was reported in either arm.

The rate of DVT was 8.7% in the mechanical compression group and 7.2% in the combined group ($P=0.57$).

Four trials had the control group as anticoagulant.

No PE was reported.

The rate of DVT was 9.71% in the anticoagulant group and 0.94% in the combined group. ($P=0.0004$).

CONCLUSION:

The addition of intermittent compression augments the efficacy of anticoagulation in the prevention of DVT in both TKR and THR.

STRENGTHS:

This is a relevant, heavily debated topic with issues including the high cost of prevention and the effects of DVT and PE, as well as the side effects of anticoagulants (bleeding and post-operative wound problems).

The study is a systematic review and meta-analysis, representing level one evidence.

It includes all the known papers comparing the two modalities.

Well-defined outcomes.

No conflicts of interest.

Appropriate statistical methodology.

LIMITATIONS:

The rate of DVT in the combined group after THR was once found to be 7.2% (when compared with mechanical compression alone) and the found to be 0.94% (when compared with anticoagulation alone), representing a significant discrepancy. No explanation was offered for this.

The durations of mechanical compression and anticoagulation treatments in the studies were not stated.

Grouping all mechanical compression methods may have masked any differential efficacies of the individual mechanical devices.

Likewise, grouping all pharmacological thromboprophylaxis methods may mask differential efficacies.

SUMMARY:

This is a well-presented attempt at answering the question of the benefit of the mechanical compression in relation to the prevention of DVT and PE. Its main limitations are due to the lack of large studies, and the varied anticoagulants and mechanical compression devices used in the studies. Its conclusion that the addition of mechanical compression augments the efficacy of pharmacological thromboprophylaxis is valid, based on the available data, and should influence practice.