ORTHOPAEDIC SURGERY



Reduced wound leakage in arthroplasty with modified wound closure: a retrospective cohort study

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Abstract

Introduction Wound leakage has been shown to increase the risk of prosthetic joint infections (PJIs) in primary total hip (THA) and knee arthroplasty (unicondylar and total knee arthroplasty; KA). The aim of this study is to determine whether the addition of a continuous subcuticular bonding stitch to a conventional three-layer closure method reduces the incidence of prolonged wound leakage and PJIs after THA and KA.

Materials and methods This retrospective cohort study included all patients receiving a THA or KA. Patients in the control group with a three-layer closure method had surgery between November 1st 2015 and October 31st 2016, and were compared to the study group with a four-layer closure method that had surgery between January 1st 2017 and December 31st 2018. The primary outcome was incidence of prolonged wound leakage longer than 72 h. Differences were evaluated using logistic regression. Incidence of PJIs was the secondary outcome.

Results A total of 439 THA and 339 KA in the control group and 460 THA and 350 KA in the study group were included. In the control group, 11.7% of the patients had a prolonged leaking wound compared to 1.9% in the study group (p < 0.001). The modified wound closure method showed a protective effect for obtaining prolonged wound leakage; odds ratios were 0.09 (95% CI 0.04–0.22; p < 0.001) for THA and 0.21 (95% CI 0.10–0.43; p < 0.001) for KA. PJIs decreased from 1.54 to 0.37% (p = 0.019).

Conclusions The addition of a continuous subcuticular bonding stitch reduces the incidence of prolonged wound leakage and PJIs after THA and KA compared to a conventional three-layer wound closure method. The large reduction of incidence in wound leakage and PJIs in this study, combined with relatively negligible cost and effort of the modified wound closure method, would advocate for implementing this wound closure method in arthroplasty.

Keywords Wound leakage · Wound closure · Infection prevention · PJI · Arthroplasty

Introduction

Prosthetic joint infections (PJI) are one of the most serious and devastating surgical complications after total joint arthroplasty (TJA) [1-3] and have a huge impact in terms of morbidity, mortality, and medical costs [4-8]. Prolonged wound leakage after arthroplasty is highly associated with an increased risk of PJIs [9-11]. The risk of PJIs increases with 42% for total hip arthroplasty (THA) and 29% for total

R. L. Roerdink r.roerdink@hotmail.com knee arthroplasty (TKA) for each day of prolonged wound leakage [10].

Reducing the prevalence of prolonged wound leakage may positively impact the prevalence of PJIs [9, 10]. A modified wound closure method might be an important factor in decreasing the incidence of prolonged wound leakage. One cadaveric study compared a closure method with interrupted conventional stitches with a running bidirectional barbed stitch [12]. The running bidirectional barbed stitch method was significantly more watertight than the interrupted conventional stitches [12]. There are no clinical studies comparing wound closure methods in patients nor are there studies that aim to reduce prolonged wound leakage after TJA.

The aim of this study is to determine whether the addition of a continuous subcuticular bonding stitch to a conventional three-layer closure method reduces the incidence

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of prolonged wound leakage after primary hip and knee arthroplasty. A secondary aim is to evaluate if the addition of a continuous subcuticular bonding stitch influences the incidence of PJIs. We hypothesized that adding a continuous subcuticular bonding stitch leads to a decrease of prolonged wound leakage and consequently a decrease of PJIs.

Materials and methods

In this retrospective cohort study, two groups were compared to assess if the addition of a continuous subcuticular bonding stitch could decrease prolonged wound leakage after primary unicondylar knee arthroplasty (UKA), TKA and THA. The continuous subcuticular bonding stitch was placed in the top layer of the subcutis predominantly consisting of connective tissue (Figs. 1, 2). The UKA patients are combined with the TKA patients as one group; knee arthroplasty (KA). THA was placed using a posterolateral approach or an anterior supine intermuscular (ASI) approach. UKA was placed using an anteromedial incision and TKA was placed by a midline incision. It was assumed not to find any differences in developing wound leakage between the approaches for THA, UKA and TKA. A sensitivity analysis was performed and if inconsistencies were present, the groups would be separated. This study is outside the scope of the Medical Research involving Human Subject Act, as declared by the Medical Ethical Review Committee Brabant (NW2018-17).

Participants

All patients undergoing primary THA and KA between November 1st 2015 and October 31st 2016 (control group) and between January 1st 2017 and December 31st 2017 (study group) were included in this study (Fig. 1). This includes patients with osteoarthritis, avascular necrosis of the femoral head, conversion from dynamic hip screws or intramedullary nails, osteolytic bone because of malignancy, femoral neck fractures and patients that had prior surgery, such as arthrotomy and arthroscopy of the operated joint. In case of previous joint surgery, infections were ruled out by pre-operative cultures obtained with aspiration of the joint. In case of infection, arthroplasty was not performed. There were no exclusion criteria.

Setting

Our hospital is a peripheral teaching hospital that provides medical care to a service area of a combined urban and rural area of 360,000 inhabitants. The department intended to reduce the amount of PJIs in THA and KA in 2017 and as a result adjusted the method of wound closure. A threelayer wound closure method was the standard procedure

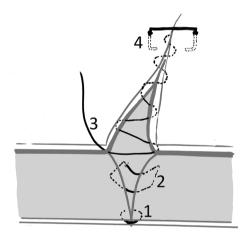


Fig. 2 Schematic representation of the four-layer closure method. (1) Fascia: stand-alone stitches; (2) subcutaneous adipose tissue: separated matrass stitches; (3) subcuticular: continuous bonding stitch (i.e., the added layer central to the study); (4) dermis: staples

Fig. 1 Overview of the layer closure method in hip and knee arthroplasty	Control group (3-layer) November 1st 2015-October 31st 2016	Study group (4-layer) January 1 st 2017-December 31 st 2017
	1. <u>Fascia:</u> stand-alone stitches (Ethicon Vicryl 2)	1. <u>Fascia:</u> stand-alone stitches (Ethicon Vicryl 2)
	2. <u>Subcutaneous adipose tissue:</u> separated matrass stitches (Ethicon Vicryl 0)	2. <u>Subcutaneous adipose tissue:</u> separated matrass stitches (Ethicon Vicryl 0)
		3. <u>Subcuticular:</u> Continuous bonding stitch (Ethicon Vicryl 2-0)
	3. <u>Dermis:</u> Staples	4. <u>Dermis:</u> Staples

for the orthopaedic surgeons during closure of THA or KA until November 1st 2016 (Fig. 1). From January 1st 2017, all orthopaedic surgeons in our hospital added a continuous subcuticular bonding non-barbed standard Ethicon 2.0 stitch to their conventional closure method (Fig. 1).

All arthroplasties were performed by experienced orthopaedic surgeons and no drains were used. The standard anticoagulant for thromboprophylaxis was 0.3 ml of nadroparin [7500 anti-Xa Choay units (2850 IU)]. Clopidogrel, therapeutic direct oral anticoagulants and coumarin were stopped prior to surgery and restarted 3 days after.

The initial wound dressing was consistent throughout the study; all patients received an AquacelTM surgical (Convatec, Greensboro, NC, USA) on their wound directly after wound closure whilst still in the sterile field. The AquacelTM is a dressing with an adhesive hydrocolloid bordering a hydrofiber core [13]. In the control group, the AquacelTM was left in place until 5-7 days after surgery and in case of blood or fluid leaking from the dressing it was removed and a new AquacelTM was placed. In case of additional leakage, the AquacelTM was removed and absorbable bandages were placed. In the study group, the AquacelTM was left in place until day 10 after surgery. In case of blood or fluid leaking from the dressing within the first 72 h after surgery, absorbable bandages were placed while keeping the AquacelTM in situ. These bandages and the AquacelTM were removed 72 h post-operative and the wound was then assessed for 2 min for wound leakage. A PICOTM (Smith and Nephew, London, UK), which is a negative pressure wound therapy device, was placed on leaking wounds, and a new clean AquacelTM was placed on dry wounds. No other changes in infection prevention measures and surgical protocols were made during the study period.

Variables

The primary outcome of this study was the incidence of prolonged wound leakage. Within current literature, there are large inconsistencies in defining 'wound leakage' [10, 11, 14, 15] as well as 'prolonged' [9, 14–19]. We based 'prolonged wound leakage' on the consensus of the Work-group of the Musculoskeletal Infection Society (WMIS) [2], which is any leakage longer than 72 h after wound closure. No distinction was made between minimal or major leakage.

Patient-related characteristics such as a higher body mass index (BMI), diabetes, smoking and usage of anticoagulants have been shown to be an independent factors influencing wound leakage [10, 20–22]. These variables are therefore assessed at baseline for differences between the groups as possible confounding variables. Other patient characteristics that are assessed as possible confounders are age, gender, the approach for THA (posterolateral or ASI) and type of KA (TKA or UKA). Additionally, a secondary outcome was the incidence of acute PJIs. Acute PJIs were defined as PJIs within 90 days after surgery. They were registered including the microorganisms found. Complications possibly related to the subcuticular stitch, such as local skin reactions, delayed wound healing and wound dehiscence, were also registered. Baseline data were collected from the Dutch Arthroplasty Register. The presence of prolonged wound leakage and complications were derived from the electronic medical files.

Statistical methods

First, we assessed if there was a significant difference in the proportion of the primary outcome wound leakage between groups. Additionally, an odds ratio (OR) of wound leakage between the two groups was calculated using logistic regression. Possible differences in baseline characteristics such as gender, age, BMI, smoking, diabetes, anticoagulants and type of surgery between groups were assessed using a t test or Chi square test for continuous or dichotomous measures, respectively. Variables found to significantly differ between groups at baseline were added to the logistic regression model to be assessed as confounder. In the event that the addition changed the original OR > 10%, the confounder was kept in the model. The incidence of PJIs was evaluated using a Fisher's exact test. All statistical tests were considered significant at the 0.05 threshold. SPSS for Windows (Version 22.0, Armonk, NY: IBM Corp.) was used for all analyses.

Results

A total of 1588 patients were included in the study. The control group consisted of 439 THA and 339 KA and the study group consisted of 460 THA and 350 KA (Table 1). The number of smokers, ASI approach and number of UKA were found to be significantly higher in the study group (p < 0.05). However, none of these possible confounders influenced the OR with > 10% and therefore the model was not adjusted. No other significant differences in the registered baseline characteristics were present.

A significant difference in the incidence of prolonged leaking wounds was found between the study group and the control group (p < 0.001) (Table 2). ORs show the modified wound closure method has a protective effect for obtaining prolonged wound leakage compared to the conventional three-layer method (Table 2).

The incidences of PJIs of all THA and KA together have been found to be significantly lower using the four-layer closure method (p = 0.019) (Table 3). Evaluating incidences of PJIs for THA and KA separately, the reductions in the four-layer group are not significant (p = 0.059 and p = 0.210, respectively). The micro-organisms detected

Table 1 Baseline characteristics

	Control group $(n=778)$	Study group ($n = 810$)	p value*
			0.540
Female, n (%)	481 (61.8)	496 (61.2)	0.560
Age (years), mean (SD)	69.2 (9.5)	69.9 (9.7)	0.155
BMI, mean (SD)	28.5 (4.7)	28.1 (4.8)	0.051
Smoking, n (%)	70 (8.9)	115 (14.2)	0.002
Missing, n (%)	28 (3.6)	4 (0.5)	
Diabetes, n (%)	86 (11.1)	103 (12.7)	0.307
Anticoagulants, n (%)	225 (28.9)	266 (32.8)	0.076
Platelet inhibitors, n (%)	168 (74.7)	187 (70.3)	
Coumarin, n (%)	50 (22.2)	67 (25.2)	
DOAC, <i>n</i> (%)	7 (3.1)	12 (4.5)	
THA, <i>n</i> (%)	439 (56.4)	460 (56.8)	< 0.001
PLA, n (%)	400 (91.1)	356 (76.4)	
ASI, n (%)	39 (8.9)	104 (22.6)	
KA, <i>n</i> (%)	339 (43.6)	350 (43.2)	0.035
TKA, <i>n</i> (%)	295 (87.1)	284 (81.1)	
UKA, <i>n</i> (%)	44 (12.9)	66 (18.9)	

SD standard deviation, BMI body mass index, THA total hip arthroplasty, PLA posterolateral approach, ASI anterior supine intermuscular approach, KA knee arthroplasty, UKA unicondylar knee arthroplasty, TKA total knee arthroplasty

*Significant difference between control and study group, p < 0.05

in the patients' cultures are listed in Table 3, some PJIs contained multiple micro-organisms.

There was one case in THA of a local skin reaction in the study group that was possibly related to the continuous subcuticular bonding stitch; the patient had local itching redness around the wound which resolved spontaneously after 10 days.

n (total) % (95% CI)

Discussion

Because of the serious consequences of PJIs, the development and application of preventive measures are of great importance. The association between wound leakage and obtaining a PJI is described as clinically relevant [9–11]. Our study aimed to evaluate the effect of adding a continuous subcuticular bonding stitch on wound leakage and PJIs.

The addition of a continuous subcuticular bonding stitch to a three-layer closure method in THA and KA highly reduces the incidence of prolonged wound leakage. The incidence in the control group was 11.7% which is comparable to an incidence of wound leakage up to 10% as described in the Second International Consensus Meeting on Prosthetic Joint Infection document [23]. The incidence found by the reviewers of the Second International Consensus Meeting document is slightly lower, but this might be explained by under-reporting of wound leakage in the reviewed studies. Unfortunately, under-reporting of wound leakage in medical registries is a common problem [24, 25]. The incidence of wound leakage in our study group was 1.9%. This amounts to a significant protective effect of the modified wound closure method for obtaining wound leakage (OR 0.14; p < 0.001).

In current literature, we found two studies [12, 26] that evaluate a closure method which aimed to be more watertight and the results of our study are in line with both of them [12, 26]. The cadaveric study of Nett et al. [12] compared a closure of a running bidirectional barbed stitch (no. 2 PDO Quill SRS) to interrupted conventional stitches (0-Vicryl) over a simulated tense hemarthrosis of the knee [12]. By simulating hemarthrosis, comparable to a postop TKA, they showed that the running bidirectional barbed stitch method was significantly more watertight [12]. El-Gazzar et al. [26] found that applying skin glue on top of staples, hypothetically creating a watertight layer, in patients with TKA greatly reduced the amount of fluid leaking from the wound within the first 3 days after surgery [26]. Other

0.21 (0.10-0.43)

p value*

< 0.001

< 0.001

< 0.001

of wound		Control group	Study group	OR (95% CI)
	All			
	n (total)	91 (778)	15 (810)	0.14 (0.08-0.25)
	% (95% CI)	11.7% (9.6–14.1)	1.9% (1.1-3.0)	
	THA			
	n (total)	49 (439)	5 (460)	0.09 (0.04-0.22)
	% (95% CI)	11.2% (8.5–14.6)	1.1% (0.4–2.7)	
	KA			

12.3% (9.1-16.4)

42 (339)

OR odds ratio, *CI* confidence interval, *THA* total hip arthroplasty, *KA* knee arthroplasty *Significant p < 0.05

10 (350)

2.9% (1.5-5.4)

 Table 2
 Incidence of wound

 leakage
 Incidence of wound

 Table 3
 Incidence of prosthetic joint infections (PJIs) and detected micro-organisms

	Control group	Study group	p value*
All n (%)*	12 (1.54)	3 (0.37)	0.019
THA n (%)	8 (1.82)	2 (0.43)	0.059
KA n (%)	4 (1.17)	1 (0.29)	0.210
Micro-organisms (n)	Staphylococcus aureus (5) Enterococcus faecalis (3) Staphylococcus epidermidis (2) Staphylococcus capitis (1) Serratia marces- cens (1) Klebsiella pneu- monia (1) Streptococcus dysgalactiae (1) Streptococcus haemolyticus (1) Streptococcus oralis (1) Pseudomonas spp. (1)	Enterococcus faecalis (2) Staphylococcus epidermidis (1)	

THA total hip arthroplasty, KA knee arthroplasty *Significant p < 0.05

studies mainly focused on the types of stitch materials used like staples, adhesives and barbed versus non-barbed stitches and therefore are incomparable to our study [23]. Also, prolonged wound leakage is rarely a primary outcome measure despite the strong relationship with PJIs [10, 23, 26]. The Second International Consensus Meeting on Prosthetic Joint Infection (ICM) states: 'Although several randomized clinical trials (RCTs) are available, surgeons primarily select wound closure systems based on personal preference. The ultimate goal is to use a wound closure system that balances cosmetic appearance, clinical outcomes, and cost-effectiveness' [23]. Our study could contribute in achieving this goal.

The secondary and most clinically relevant outcome of this study would be the number of PJIs. PJIs are one of the most serious complications in THA and TKA [1–3]. It affects the patients' quality of life and their ability to return to daily routine [7, 27]. Moreover, PJIs have a serious economic impact, with the costs of treatment estimated to be three to four times the cost of a primary TJA [4–6, 28]. Our study shows a significant overall decrease in PJIs for THA and KA combined from 1.54% in our control group to 0.37% in our study group. The latter is lower than the mentioned incidence of 1–3% for primary THA and KA within current literature [27, 29]. A decrease of both wound leakage

and PJIs supports the association between these variables. However, association in itself does not necessarily imply causation. An adjustment in post-operative wound care for the study group in addition to the modified wound closure method is likely to have influenced the incidence. Also, the results of this study are underpowered for PJIs as primary outcome. To obtain a large enough sample size to draw firm conclusions about PJIs, we would have to expand the cohort and still minimize other possible confounders. Due to other changes made in the past to reduce PJIs, expanding the cohort was not possible.

The outcomes of this retrospective cohort study are based on medical files, which might be an important limitation. In the control group, only when wound leakage was specifically noted, patients where marked as such. Within the control group, some patients were discharged 2 days after surgery with a leaking wound without follow up in the consecutive days. Also, some medical files did not report any notes about the wound during hospital admission or outpatient follow up. In these cases, or if there was any doubt, the patients were marked as non-leaking wound in this group. This might have led to under-reporting in the control group. Data for the study group were collected prospectively and then retrospectively checked the same way as data for the control group. In the study group, patients with early onset wound leakage were kept admitted at least 72 h after surgery instead of discharging them on the 1st or 2nd day after surgery. This makes under-reporting in the study group highly unlikely. Therefore, the reported protective effect of the continuous subcuticular bonding stich is conservative and could actually be larger.

Like any surgical skill or method, differences between orthopaedic surgeons are to be expected in suture interval. Due to the pragmatic nature of this study, this was not objectified.

The registered PJIs that were found in this study were checked with two other available registries, one independent register from the infection prevention department that is connected to a national database for PJIs and a local infection register. No inconsistencies were found, so under-reporting of PJIs can be ruled out.

Conclusion

This study shows the addition of a continuous subcuticular bonding stitch reduces the incidence of prolonged wound leakage and PJIs after THA and KA compared to the conventional three-layer wound closure method. The reduction of incidence in wound leakage and PJIs in this study, combined with relatively negligible cost of and effort for the modified wound closure method, would advocate implementing this wound closure method in arthroplasty. Acknowledgements We would like to thank Rebecca McIntyre for reviewing this article as native speaker. We would like to thank Joost Guttinger for designing Fig. 2. And we would like to thank all orthopaedic surgeons of our department, N. Verschoor, D. A. Dartee, C. M. Douw, H. K. M. Hamelinck, D. J. van Doeselaar, D. van Oostveen, H. J. T. A. M. Huijbregts and N. Bennink for making this study possible.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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