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ORIGINAL ARTICLE • LOWER LIMB - FRACTURES

Tourniquet use in lower limb fracture surgery: a systematic review and meta-analysis

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Abstract

Background Tourniquets are commonly used in today's orthopaedic surgical practice, but little evidence is available regarding the links between the use of a tourniquet and the amount of post-operative pain and other complications. The aim of the study was to conduct a systematic review and meta-analysis comparing tourniquet versus non-tourniquet use during fracture surgery of the lower limb in adult patients.

Method A search was performed using the keyword "tourniquet" in EmBase and as a MeSH term in PubMed, and no limitations (including language) were applied. Available studies were screened using the Covidence software, and demographic as well as outcome data were extracted from the final studies. Critical appraisal was performed according to Cochrane Risk of Bias guidelines. Pooled data were assessed for heterogeneity using Chi-squared and I^2 tests.

Results Five studies were included, and no statistically significant difference was found in the amount of pain and post-operative complications between tourniquet and non-tourniquet groups. Length of in-hospital stay was longer in the tourniquet groups. An overall high risk of bias was found in the included studies.

Conclusion Although the validity and statistical strength of our results are not strong enough to suggest a change in practice in tourniquet use, the operating surgeon should still carefully consider his or her decision to use a tourniquet in lower limb fracture surgery, as there are indeed complications associated with it and no current evidence to support its continued use.

Level of evidence Level I, systematic review of randomized controlled trials.

Keywords Tourniquet · Fracture · Lower limb · Complication · Pain

Introduction

Tourniquets have commonly been used in fracture surgery to provide a bloodless field and therefore improve visualization, shorten operation time and decrease blood loss [1]. Unfortunately, the very use of a tourniquet may lead to complications such as blistering, skin necrosis and nerve complications such as paresis, rhabdomyolysis, compartment syndrome and deep vein thrombosis [2–5]. In today's orthopaedic surgical practice, the decision to operate with or without a tourniquet is more often than not dependent on the operating surgeon's personal preference. The question is therefore whether a tourniquet is a necessary tool in orthopaedic fracture surgery or not.

In 2010, Smith and Hing [6] conducted a systematic review with meta-analysis comparing tourniquet use to non-tourniquet use in foot and ankle surgery, demonstrating less post-operative pain in the non-tourniquet group as well as less swelling up to 6 weeks after surgery and a shorter length of stay. However, because of a low methodological quality of evidence, they ultimately concluded that further research was needed in order to determine whether a change in practice in tourniquet use was appropriate. In addition, no meta-analyses were performed, due to a low number of included studies.

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When choosing to do surgery on lower limb fractures with or without a tourniquet, surgeons must be aware of the potential harms and benefits.

Our aim was therefore to conduct a systematic review and meta-analysis comparing tourniquet with non-tourniquet use during fracture surgery of the lower limb in adult patients in terms of pain and complications.

Methods

Protocol and registration

The study is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statements [7]. The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (ID: 80608) before data extraction was performed.

Eligibility criteria

Randomized controlled trials (RCTs) comparing tourniquet with non-tourniquet surgeries on fractures of the lower limb with pain or complications as outcome were included. Other study designs were excluded if two or more RCTs existed, thereby avoiding extending the scope of this systematic review. Studies with elective procedures or non-fracture surgery were excluded as well as the paediatric population.

Information sources

Two review authors searched the PubMed and EmBase databases for all results until the 1 September 2017, in cooperation with a library search technician. The reference lists of included studies and Clinicaltrials.gov were scanned for additional eligible studies.

Search

A simple but exhaustive search was performed using the keyword "tourniquet" in EmBase and as a MeSH term in PubMed. No limitations (including language) were applied.

Study selection

The search results were uploaded to the web-based screening software at Covidence.org. Two review authors independently reviewed all 7473 preliminary results and screened according to title, abstract and finally full text, utilizing the aforementioned inclusion and exclusion criteria. Any discrepancies for each step were resolved before proceeding to the next step.

Data collection process

One review author manually designed a data extraction sheet depending on the individually available data from each included study and extracted the relevant data. A second author cross-checked the extracted data. Konrad et al. [8] were contacted for additional data since the data were only presented graphically, but unfortunately no response was received within our time frame.

Data items

Primary data extraction concerned only outcome measures relevant to our particular review, comparable measures of post-operative pain and post-operative complications. We defined post-operative complications as infections, deep vein thrombosis (DVT) and non-union.

Secondary data extraction concerned all available data on study-specific methods regarding (1) study characteristics (country of origin, study design, number of participants and length of follow-up), (2) characteristics of study participants (age, sex, fracture type and length of stay in hospital) and (3) operation characteristics (data on the use of a tourniquet and surgery duration.)

Risk of bias in individual studies

The risk of bias assessment in the included RCTs was performed using the Cochrane Risk of Bias Tool [9]. Two collaborating review authors assessed the studies in unison, and the findings were checked by a third author.

Summary measures

Primary outcomes, pain and number of complications were reported across the studies and meta-analysed using Forest plots. Weighted mean difference and 95% confidence intervals for each study were calculated. Pain was measured either by visual analogue scale or by the intervention effect and was expressed as a risk ratio for number of complications and mean difference for pain. A p value < 0.05 was considered statistically significant. Statistical analysis was performed using the software Revman 5.3.

Meta-analysis was performed by computing relative risks (RR) for one forest plot (Fig. 1) and data set, and mean difference for the other forest plot (Fig. 2) and data set. RR was chosen as the effect for complications due to the nature of the data, i.e. events in groups compared with one another. Correspondingly, mean difference was

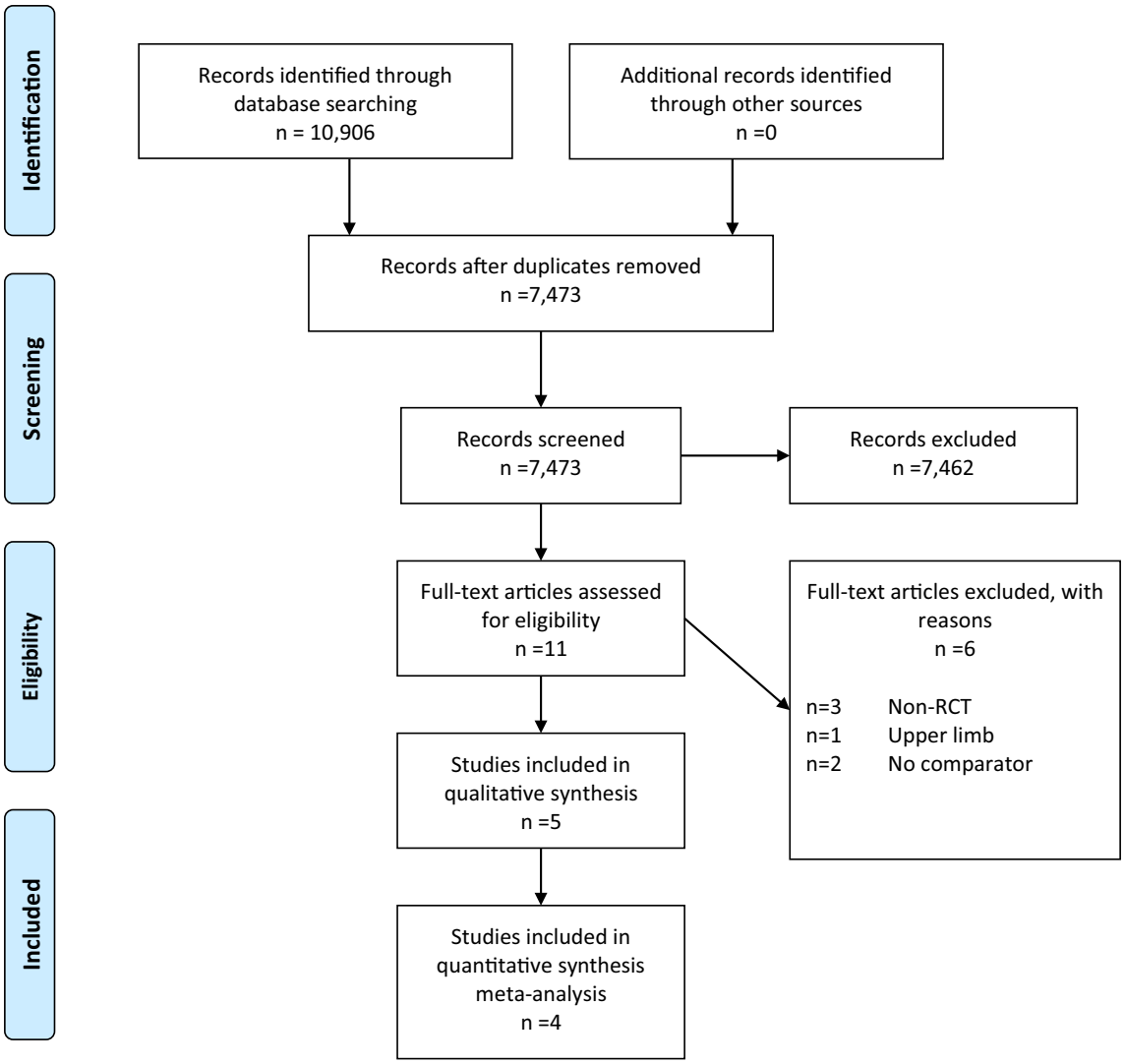

Fig. 1 PRISMA flow diagram of the screening process

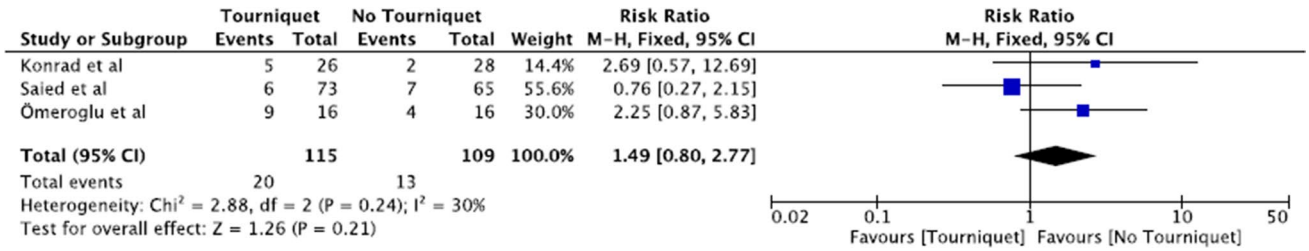

Fig. 2 Analysis of complications associated with surgery

used for the data set consisting of self-reported pain since it was reported on two different scales. The data set from Ömeroglu et al. [10] was converted from a 1–5 scale to a 1–10 scale (visual analogue scale).

Synthesis of results

Pooled data were assessed for heterogeneity using Chi-squared and I^2 tests. Heterogeneity was defined as absent between 0 and 25%, low between 26 and 50%, moderate

between 51 and 75% and high between 75.1 and 100%. As there was no evidence of heterogeneity among studies ($p > 0.1$ and $I^2 < 50\%$), a fixed effect meta-analysis was performed.

Statement of human and animal rights

This article does not contain any studies with human participants or animals performed by any of the authors.

Results

Study selection

After removal of duplicates, 7473 studies were screened (Fig. 1). Eleven studies remained, of which three non-RCTs, two studies without a comparator group and one study focusing on the upper limb were excluded. Five articles were included in the systematic review, but only four of these were included in the meta-analysis. Salam et al.' study [11] was excluded from meta-analysis due to difficulty comparing outcome data.

Study characteristics

Three studies included ankle fractures and two included tibial fractures. The length of follow-up varied greatly from 2 days to 32 months. The included number of participants ranged from 32 to 138, and except for one study (Konrad et al. [8]), there was a surplus of males included. The mean age ranged from 40 to 52 (Table 1).

Risk of bias within studies

Due to the nature of these studies, blinding of the operating surgeon is almost impossible, and no studies specified further blinding of personnel or participants. In general, the included studies reported very little methodological avoidance of risk of bias, and thus, many single assessments have been denominated as "Unclear" (Table 2).

Synthesis of results

In the analysis for complications associated with surgery (Fig. 2), the risk ratio [95% confidence interval] was 1.49 [0.8, 2.77], yielding no difference ($p < 0.21$). The second analysis for 24 h post-operative pain (Fig. 3) demonstrated a mean difference of 0.8 [0.38, 1.23] in favour of non-tourniquet ($p < 0.00002$).

Konrad et al. [8] and Maffulli et al. [12] found longer lengths of post-operative stay in the tourniquet groups. In Konrad et al. [8], the difference was statistically significant ($p < 0.05$). Konrad et al. [8] found no difference in the duration of surgery, while Saied and Zyaei [13] found a statistically significant longer duration of surgery in the

Table 1 Study characteristics of the included studies

Study	Country	Fracture type	Follow-up	Tourniquet			Non-tourniquet		
				n	Mean age (SD)	*M*/*F* %	*n*	Mean age (SD)	*M*/*F* %
Konrad et al. [8]	Germany	AO 44-B/C	6 weeks	26	42.7 (9.3)	38/62	28	41.6 (8.7)	39/61
Mafulli et al. [12]	Italy	AO 44-A1/B1/C1	9–32 months	40	52 (6.4)	83/17	40	50 (7.9)	73/27
Ömeruğlo et al. [10]	Turkey	AO 44-A/B/C	1 and 2 days	16	40 (15)	63/37	16	37 (16)	75/25
Saied and Zyaei [13]	Iran	Simple extraarticular tibial fracture	1 day and 1 year	73	39.7 (12.6)	80/20	65	39.4 (12.5)	80/20
Salam et al. [11]	UK	Closed tibial fractures	3 weeks	30	N/A	N/A	30	N/A	N/A

AO Arbeitsgemeintshaft für Osteosynthesefragen, *SD* standard deviation, *M*/*F* male/female

Table 2 Risk of bias table

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting
Konrad et al. [8]	Unclear	Unclear	Unclear	Low	Low	Unclear
Ömeruglu et al. [10]	High	Unclear	Unclear	Unclear	Unclear	Unclear
Saied and Zyaei [13]	Low	High	Unclear	Low	Unclear	Unclear
Salam et al. [11]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Mafulli et al. [12]	Low	Unclear	Unclear	Low	Low	Unclear

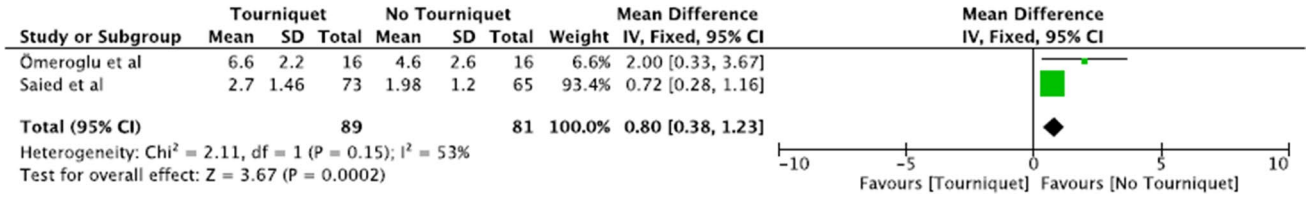

Fig. 3 Analysis of post-operative pain within 24 h

Table 3 Duration of surgery and length of stay

Study	Tourniquet			Non-tourniquet		
	Length of stay (SD)	Duration of surgery (SD)	Deep vein thrombosis (*n*)	Length of stay (SD)	Duration of surgery (SD)	Deep vein thrombosis (*n*)
Konrad et al. [8]	12.4 (9)	56 (–)	1	8.6 (4.4)	52 (–)	0
Mafulli et al. [12]	12 (5.1)		2	9 (4)		0
Saied and Zyaei [13]		49.5 (9.2)			55.2 (11)	

SD Standard deviation. Length of stay in days. Duration of surgery in minutes

non-tourniquet group (Table 3). Concerning deep vein thromboses (DVT), Konrad et al. [8] found one DVT in the tourniquet group and Maffulli et al. [12] found two DVTs in the tourniquet group. Neither had DVTs in the non-tourniquet group, but the differences were not statistical significant.

Discussion

In regard to post-operative pain, the meta-analysis revealed a lower mean difference in the non-tourniquet group, with a VAS score of 0.8 less than in the tourniquet group. To be certain that this difference is clinically relevant, we first need to know the minimal detectable change (MDC), which reflects the smallest within-person change in a score that can be interpreted as real and statistically significant [14]. We found no studies estimating the MDC in fracture surgery, but two other studies demonstrated that the MDC for a VAS score ranging from 1 to 10 was approximately 2 points [15, 16]. A 0.8 point difference is therefore not clinically relevant. Moreover, the studies included in this analysis were heavily unbalanced and both were considered to have a high risk of bias overall.

In a retrospective observational study from 2015 by Kruse et al. [17], it was demonstrated that the amount of opioids used post-operatively increased proportionately with tourniquet time in surgery of calcaneal fractures. As secondary findings they reported an increase in peak pain score, and time in the post-anaesthetic care unit also increased with tourniquet time. The magnitude of the secondary findings was, however, small and possibly of limited clinical significance.

In a non-fracture randomized controlled trial, Zhou et al. [18] demonstrated a better post-operative recovery when comparing tourniquet to non-tourniquet in total knee arthroplasty. They reported statistically significant results, showing less thigh pain in the first three weeks and a shorter length of stay in the group where non-tourniquet was used.

Kumar et al. [19] had similar findings in a randomized controlled trial of bilateral total knee replacement with and without tourniquet. A statistically significant difference in mean VAS score between the groups was found during the three initial post-operative days, in favour of the non-tourniquet group. This mean difference was approximately 1.8 on the first day and smaller on the second and third days. According to the previously mentioned MDC of approximately 2 points, the difference might therefore be clinically relevant.

Despite the possibly limited significance and magnitude of the findings in this study and the secondary findings in Kruse et al. [17], the findings still support the hypothesis that tourniquets increase post-operative pain and length of in-hospital stay. As mentioned before, this study also found a shorter length of stay in the non-tourniquet groups in two of the included studies. Hence, together with the current analysis, all three studies (Kruse et al. [17], Zhou et al. [18] and Kumar et al. [19]) point in the same direction in favour of non-tourniquet.

When considering the complications associated with surgery, the overall effect in the analysis of this study favoured the treatment "non-tourniquet", but this was not statistically

significant. Konrad et al.' study [8] was also included in this analysis, which has fewer issues with risk of bias. Overall, the risk of bias is still quite high, again lowering the validity of the results.

Su et al. [20] demonstrated a higher incidence of wound complications in calcaneal fractures with higher tourniquet times in an observational study of 318 fractures. In a systematic review from 2014 on total knee arthroplasty (TKA), Zhang et al. found that the use of a tourniquet in TKA increased the risk of thrombotic events (DVT and pulmonary embolism) and non-thrombotic events (blister, infection, haematoma, nerve palsy, bruising, wound oozing and re-operation) [21].

Odinsson and Finsen [2] retrospectively investigated the neurological complications following tourniquet use in lower limb fracture surgery. Their findings suggest that tourniquet time is an important factor in regard to these post-operative complications, recommending that surgeons adhere to a maximum inflation time of 2 h to reduce the incidence of permanent nerve damage.

Not only tourniquet time, but also tourniquet cuff pressure (TCP) can have an impact on post-operative complications. Olivecrona et al. [22] investigated the link between nerve damage and TCP in total knee arthroplasty (TKA) in a neurophysiological RCT in 2013 and found that a TCP of ~ 280 mmHg for up to 80 min was safe in regard to neurological injury in patients undergoing TKA in a bloodless field. One patient with a higher TCP of 294 for 100 min showed signs of recent denervation demonstrated through electromyography and clinical signs of nerve injury.

Although patients in the tourniquet groups may have slightly shorter durations of surgery, they have a longer hospitalization time after the surgery. Hence, the use of a tourniquet cannot be rationalized from a cost-effectiveness perspective, as a few minutes saved in the operating room does not outweigh the increased cost of longer hospitalization time, nor is it desirable from the patients' point of view. The cumulative costs of using disposable tourniquets are not to be neglected either. Thus, for a surgeon to ethically justify the use of a tourniquet, which may cause complications in and of itself, there would have to be an advantage greater than the potential additional complications. The current literature does not seem to justify this.

A clear limitation of this review is the overall high risk of bias in all included studies. Furthermore, few studies are included in the two meta-analyses (two and three, respectively) which is apparent in the heterogeneity score.

In perspective, the current studies are not adequately powered to address differences in low-frequency complications and future large cohort or registry studies are therefore warranted.

We conclude that although the validity and statistical strength of our results are not strong enough to suggest a change in practice in tourniquet use, the operating surgeon should still carefully consider his or her decision to use a tourniquet in lower limb fracture surgery, as there are indeed complications associated with it and no current evidence to support its continued use.

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Compliance with ethical standards

Conflict of interest All authors declare that no financial or personal relationships with other people or organisations exist that could inappropriately influence the work in this study.

References

1. Sato J, Ishii Y, Noguchi H, Takeda M (2012) Safety and efficacy of a new tourniquet system. BMC Surg 12:17. https://doi.org/10.1186/1471-2482-12-17
2. Odinsson A, Finsen V (2006) Tourniquet use and its complications in Norway. J Bone Joint Surg Br 88-B:1090–1092. https://doi.org/10.1302/0301-620x.88b8.17668
3. Palmer SH, Graham G (1994) Tourniquet-induced rhabdomyolysis after total knee replacement. Ann R Coll Surg Engl 6:416–417
4. Hirvensalo E, Tuominen H, Lapinsuo M, Helio H (1992) Compartment syndrome of the lower limb caused by a tourniquet: a report of two cases. J Orthop Trauma 6:469–472
5. Desai K, Dinh TP, Chung S, Pierpont YN, Naidu DK, Payne WG (2015) Upper extremity deep vein thrombosis with tourniquet use. Int J Surg Case Rep 6c:55–57. https://doi.org/10.1016/j.ijscr.2014.11.055
6. Smith TO, Hing CB (2010) The efficacy of the tourniquet in foot and ankle surgery? A systematic review and meta-analysis. Foot Ankle Surg 16:3–8. https://doi.org/10.1016/j.fas.2009.03.006
7. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, Clarke M, Deveraux PJ, Kleijnen J, Moher D (2009) The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ 339:b2700. https://doi.org/10.1136/bmj.b2700
8. Konrad G, Markmiller M, Lenich A, Mayr E, Ruter A (2005) Tourniquets may increase postoperative swelling and pain after internal fixation of ankle fractures. Clin Orthop Relat Res 433:189–194. https://doi.org/10.1097/01.blo.0000151849.37260.0a
9. Higgins JP, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, Savovic J, Schulz KF, Weeks L, Sterne JA (2011) The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ 343:d5928. https://doi.org/10.1136/bmj.d5928
10. Ömeroğlu H, Günel U, Biçimoğlu A, Tabak AY, Uçaner A, Güney O (1997) The relationship between the use of tourniquet and the intensity of postoperative pain in surgically treated malleolar fractures. Foot Ankle Int 18:798–802. https://doi.org/10.1177/107110079701801208
11. Salam AA, Eyres KS, Cleary J, El-Sayed HH (1991) The use of a tourniquet when plating tibial fractures. J Bone Joint Surg Br 73:86–87

12. Maffulli N, Testa V, Capasso G (1993) Use of a tourniquet in the internal fixation of fractures of the distal part of the fibula. A prospective, randomized trial. J Bone Joint Surg Am 75:700–703
13. Saied A, Zyaei A (2010) Tourniquet use during plating of acute extra-articular tibial fractures: effects on final results of the operation. J Trauma 69:E94–E97. https://doi.org/10.1097/TA.0b013e3181dbac93
14. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, Bouter LM, de Vet HC (2007) Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 60:34–42. https://doi.org/10.1016/j.jclinepi.2006.03.012
15. Naylor JM, Hayen A, Davidson E, Hackett D, Harris IA, Kamalasena G, Mittal R (2014) Minimal detectable change for mobility and patient-reported tools in people with osteoarthritis awaiting arthroplasty. BMC Musculoskelet Disord 15:235. https://doi.org/10.1186/1471-2474-15-235
16. Stauffer ME, Taylor SD, Watson DJ, Peloso PM, Morrison A (2011) Definition of nonresponse to analgesic treatment of arthritic pain: an analytical literature review of the smallest detectable difference, the minimal detectable change, and the minimal clinically important difference on the pain visual analog scale. Int J Inflam. https://doi.org/10.4061/2011/231926
17. Kruse H, Christensen KP, Møller AM, Gögenur I (2015) Tourniquet use during ankle surgery leads to increased postoperative opioid use. J Clin Anesth 27:380–384. https://doi.org/10.1016/j.jclinane.2015.03.034
18. Zhou K, Ling T, Wang H, Hou Z, Shen B, Yang J, Kang P, Pei F (2017) Influence of tourniquet use in primary total knee arthroplasty with drainage: a prospective randomised controlled trial. J Orthop Surg Res 12:172. https://doi.org/10.1186/s13018-017-0683-z
19. Kumar N, Yadav C, Singh S, Kumar A, Vaithlingam A, Yadav S (2015) Evaluation of pain in bilateral total knee replacement and without tourniquet; a prospective randomized control trial. J Clin Orthop Trauma 6:85–88. https://doi.org/10.1016/j.jcot.2015.01.095
20. Su J, Cao X (2017) Risk factors of wound infection after open reduction and internal fixation of calcaneal fractures. Med Baltim 96:e8411. https://doi.org/10.1097/MD.0000000000008411
21. Zhang W, Li N, Chen S, Tan Y, Al-Aidaros M, Chen L (2014) The effects of a tourniquet used in total knee arthroplasty: a meta-analysis. J Orthop Surg Res 9:13. https://doi.org/10.1097/MD.0000000000008411
22. Olivecrona C, Blomfeldt R, Ponzer S, Stanford BR, Nilsson BY (2013) Tourniquet cuff pressure and nerve injury in knee arthroplasty in a bloodless field: a neurophysiological study. Acta Orthop 84:159–164. https://doi.org/10.3109/17453674.2013.782525