REVIEW

Autologous blood transfusion drainage compared with no drainage in total knee arthroplasty: A meta-analysis and systematic review

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Abstract: This is the first meta-analysis to assess the clinical efficiency, safety and potential advantages regarding the use of ABT drains compared with no drainage which is controversial in total knee arthroplasty (TKA).A comprehensive literature search was carried out in March 2015 using the PubMed, Embase, and Cochrane Library databases. A meta-analysis was carried out on two retrospective comparative studies (RCSs) and five randomized controlled trials (RCTs). The number of patients receiving homologous blood transfusion was the primary outcome of the meta-analysis; the secondary outcome measure was the mean drop in Hb level in comparison to the mean pre-operative HB level, the range of flexion of the knee joint, and infections of the wound after surgery. A total of 868 patients, who were included in two retrospective studies and five RCTs, were distributed into subgroups for the meta-analysis. This pooled data showed no benefit of ABT drainage compared no drainage in the homologous blood transfusion rate (13.05% and 16.91%, OR:0.73[0.47,1.13], Z=1.41, P=0.016;and 3.49% and 6.54%, OR: 0.50[0.12,2.01], Z=0.98,P=0.033,respectively in subgroups), Hb drop (Weight mean differences (WMD): 0.20[-0.28,0.68], Z=0.82,P=0.41;WMD:0.16[-0.41,0.55], Z=0.93, P=0.35, respectively), range of flexion of the knee joint (WMD:-0.82 [-3.35,1.70], Z =0.64,P=0.52)and wound infection (OR:0.25[0.61,10.20]; Z =1.28, p=0.2) after TKA surgery. Our findings do not recommend the routine use of postoperative ABT drainage in total knee arthroplasty. Well-designed RCTs with large sample sizes, longer term measures and extensive follow-up period should be performed in the future to update the findings of this study.

Keywords: Knee arthroplasty, Knee replacement, Autologous blood transfusion, drainage, drains.

INTRODUCTION

The most common form of arthritis is osteoarthritis (OA), which causes disabilities and an economic burden throughout the world (Neogi, 2013). Knee OA, associated with an impaired health-related quality of life, has been shown to account for 83% of the global years lived with disability that were due to presence of any OA (Alkan *et al*., 2014; Visser *et al*., 2015). Total knee arthroplasty (TKA) is a standardized highly successful procedure for this urgent knee OA. TKA can result in significant blood loss, reduction in Hb and other clinical risk (Keating *et al*., 1998; Torres-Claramunt *et al*., 2014). Autologous blood transfusion (ABT) drainage system post-TKA has become a new unwashed salvaged blood retransfusion system for primary TKA. ABT drainage consisted of evaluator tube, blood prefilter, security strap, mounting clamp and blood bag. The unwashed shed blood post-TKA was collected, filtered, stored and retransfused into the body by ABT drainage. Use of ABT drainage, no drainage or closed-suction drainage has been controversial. The need for homologous blood after ABT was significantly reduced according to some studies (Friederichs *et al*., 2002; Steinberg *et al*., 2004; Tsumara *et al*., 2006); however, the benefit of ABT was not shown in other studies (Friederichs *et al*., 2002; Steinberg *et al*., 2004; Tsumara *et al*., 2006).

Up to now, no systematic reviews incorporating meta-analyses (SRMA) have found directly sufficient evidence to recommend ABT drainage and no drainage in primary TKA. This is the first SRMA to systematically compare the clinical results of ABT drainage (autologous blood transfusion) with no drainage in patients undergoing total knee arthroplasty. Some SRMA compared ABT drainage versus closed suction drainage, closed suction drainage versus no drainage, were published as standard in evidence based medicine (Haien *et al*., 2013; Markar *et al*., 2012). Network meta-analyses were performed to assess various healthcare interventions. The basis was using a common comparator between pairwise meta-analyses. There are challenges, however, that need to be considered when carrying out a network meta-analysis (Bafeta *et al*., 2014; Cipriani *et al*., 2013; Hutton *et al*., 2014). In this study, we aimed to perform a systematic review and perform a meta-analysis to pool the data from

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studies reported in the literature, in order to provide evidence recommending the use of ABT drainage following TKA surgery.

Evidence acquisition

The Preferred Reporting Items for Systematic Review and Meta-analysis (Liberati *et al*., 2009) was used for an a priori preparation of the literature-search strategies, inclusion and exclusion criteria, objectives, outcomes and statistical methods to be used in the study.

Data sources and search strategies

To prepare for the meta-analysis, we searched the literature without restriction regarding the type of publication or the region of publication. This search was carried out in March 2015. PubMed (1950-March 2015), Embase (1974-March 2015), and the Cochrane Library (March 2015, Issue 3) were the databases that were searched. The following MeSH terms (with various combinations [Title/Abstract]) were included in the search: “total knee replacement” OR “total knee arthroplasty” OR “total knee prosthesis ”OR “unicompartmental” OR “unicondylar” OR “unicompartmenta” OR “arthroplasty, replacement, knee”[MeSH term] AND (“autologous blood transfusion” OR “Autotransfusion” OR “blood transfusion, autologous” [MeSH Terms] OR “Intraoperative Blood Salvage” OR“ Intraoperative Blood” OR “Postoperative Blood Salvage” OR “Intraoperative Blood Cell Salvage” OR “Operative Blood Salvage” [MeSH Terms]. We also searched the reference lists of related reviews and original articles identified for any relevant studies including retrospective comparative study (RCSs) and randomized controlled trials (RCTs) involving adult humans.

Inclusion and exclusion criteria

Two independent researchers (Pan and Xie) identified studies that met the defined inclusion criteria with disagreements resolved by consensus (Hong and J. Liu). The inclusion criteria were: 1) the study was a RCT or retrospective comparative study; 2) the comparison in the study was between use of ABT drainage or no drainage after TKA; 3) at least one of the outcomes listed in the next section were included in the study, and 4) the study report was published in English. Non-original research (e.g. review article, editorials, letter to the editor), case reports, animal experimental studies, and duplicated publications were excluded.

Extraction of data and analysis outcomes

Two authors (Hong and Xie) extracted the data from the studies that were determined to be eligible for the meta-analysis. They performed the task independently to reduce potential bias and minimize errors. If there was disagreement between the authors, consensus was reached with discussion. The data was then placed in a spreadsheet, and the variables included were sample size, study design, patient gender and age, pre-operative and postoperative Hb levels, range of flexion of the knee joint, number of patients that received a transfusion of homologous blood, and infection of the wound. The primary outcome was the homologous blood transfusion rate. The secondary outcomes were mean Hb drop (Hb change between mean pre-operative Hb levels and mean postoperative), range of flexion of the knee joint and wound infection.

Statistical analysis and quality assessment

Criteria set by the Centre for Evidence-based Medicine in Oxford, UK (Phillips B *et al*., 2009) were used to rate the evidence in the studies. The modified Newcastle-Ottawa scale and the Cochrane risk of bias tool were used to check the methodological quality of the included studies ((J and S, 2008; Wells G *et al*.). Except for the RCTS, each study was assigned a score of 0-9 (allocated as stars) and six or more stars suggested the study was of high quality. Cochrane Collaboration review Manager 5.3.5 (Cochrane Collaboration, Oxford, UK) was used for all statistical analyses. Weighted mean differences (WMD) with 95% confidence intervals (CI) were calculated for continuous data. Dichotomous data were analyzed by calculating the odds risk (OR) with 95% CI. A chi-squared test and I^2 statistic were calculated to assess the statistical heterogeneity. Studies with significant heterogeneity and without clinical and methodological diversity required use of a random-effects model ($P < 0.10$; $I^2>50\%$). Otherwise, a fixed-effect model was used (J and S, 2008). Subgroup analyses were performed to compare ABT drainage, no drainage with the respective publication designs. Sensitivity analyses were conducted when significant heterogeneity was identified and subgroup sensitivity analyses for determining the certainty degree of the analysis result. Results of a review are regarded with a high degree of certainty when overall result and conclusions are not affected by review process decision making (J and S, 2008). Publication bias was analyzed with funnel plots.

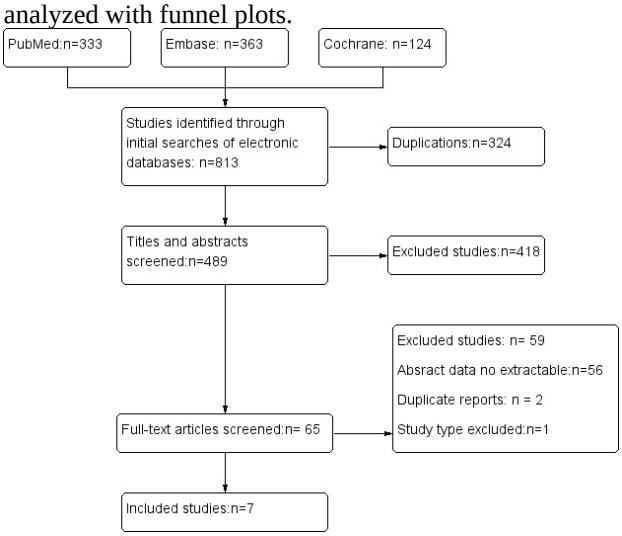

Fig. 1: Flow chart of studies that were identified, included and excluded.

RESULTS

Seven full-text articles (Adalberth *et al*., 1998; Al-Zahid and Davies, 2012; Dutton *et al*., 2012; Horstmann *et al*., 2014; Jones *et al*., 2007; Ritter *et al*., 1994; Thomassen *et al*., 2014) that were published in English fulfilled the inclusion criteria (fig. 1). These studies included a total of 868 cases with 424 cases receiving ABT drainage and 444 cases receiving no drainage. The agreement between the two reviewing authors for selecting the studies was 93% and the agreement for quality assessment was 90%.

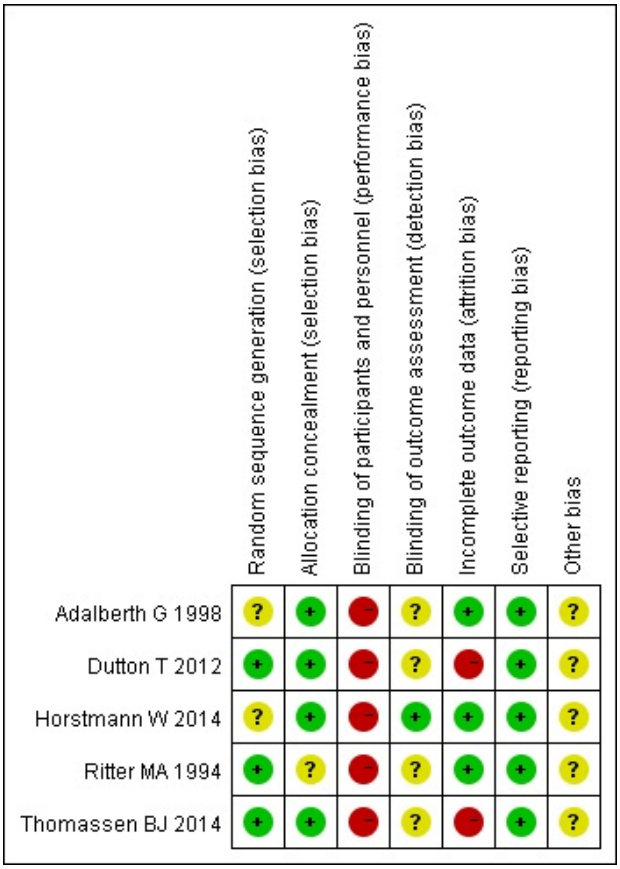

Fig. 2: Risk of bias assessment

Description of the characteristics of the eligible studies

Descriptions of the characteristics of the eligible studies are shown in table 1. The quality of the eligible studies was assessed and the quality was determined to be medium. Our results showed that true randomization was employed in only three RCTs (Dutton *et al*., 2012; Ritter *et al*., 1994; Thomassen *et al*., 2014). The randomization process was not provided in two of the RCTs (Adalberth *et al*., 1998; Horstmann *et al*., 2014). Information on whether allocation was concealed or whether subjects were assigned blindly was provided by four studies. A high risk of performance bias in blinding was included in all the studies. This was attributed to the difficulty in blinding due to use of the drainage device. No study had adopted a protocol for treatment assignment and assignment was therefore at the discretion of the physician. The majority of studies did not describe the method for handling missing data and intention-to-treat analysis adequately. The majority of the RCTs reviewed in this meta-analysis were moderate-quality studies. fig. 2 and 3 show the quality of the methodology for the RCTs, which was assessed using the Cochrane risk of bias tool.

Primary outcomes

Homologous blood transfusion rate

Severn studies (Adalberth *et al*., 1998; Al-Zahid and Davies, 2012; Dutton *et al*., 2012; Horstmann *et al*., 2014; Jones *et al*., 2007; Ritter *et al*., 1994; Thomassen *et al*., 2014) compared the effect of ABT drainage versus no drainage groups according to changes in the number of patients requiring homologous blood transfusion. The meta –analysis of Rct group (Adalberth *et al*., 1998; Dutton *et al*., 2012; Horstmann *et al*., 2014; Ritter *et al*., 1994; Thomassen *et al*., 2014) and Rcs group (Al-Zahid and Davies, 2012; Jones *et al*., 2007) showed no heterogeneity in the consistency of the results (chi-square = 1.22, P =0.87;I^2 =0% ; and chi-square = 0.37, P =0.54;I^2 =0%, respectively) and no significant beneficial effect of ABT drainage compared with no drainage in reducing the blood transfusion rate (13.05% and 16.91%, OR: 0.73 [0.47, 1.13], Z=1.41, P=0.016; and 3.49% and 6.54%, OR: 0.50 [0.12, 2.01], Z=0.98, P=0.033, respectively) (fig. 4). Nevertheless, the two groups were combined as the overall results showed no heterogeneity (chi-square =1.79, P=0.94; I^2=0%) and no significant difference between the ABT drainage and no drainage groups (11.08% and 14.41%, OR: 0.71 [0.47, 1.07], Z=1.66, P=0.10) (fig. 4). To assess any impact of study design on the effect estimates, All Rcts but no retrospective studies were included in subgroups sensitivity analysis. There was no change in the significance difference of this outcome.

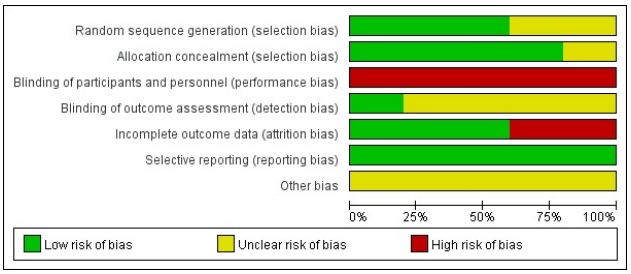

Fig. 3: Risk of bias summary

Secondary outcomes

Hb drop compared pre-operative Hb levels with mean postoperative

Three RCTs (Adalberth *et al*., 1998; Dutton *et al*., 2012; Horstmann *et al*., 2014) and two retrospective studies (Al-Zahid and Davies, 2012; Jones *et al*., 2007) reported pre-operative haemoglobin levels and the post-operative. Using the combined method described in the Cochrane Reviewer's Handbook 5.3, post-operative Hb levels for days 1-4 that were reported in two RCTs (Adalberth *et al*., 1998; Horstmann *et al*., 2014) were combined and

Table 1: Characteristics of included studies

Study	LOE *	Quality score	Sample size		Age*		Sex(M/F)		Pre-op Hb*	
			AD	ND	AD	ND	AD	ND	AD	ND
Horstmann W 2014	1b	RCT	59	56	68(9)	69(8)	17:24	39:17	14(1.4)	14(1.4)
Adalberth G 1998	1b	RCT	30	30	70(1.7)	71(1.3)	11:13	4:20	14.2(2.6)	13.8(2.6)
Dutton T 2012	2b	RCT	23	25	68.7	70.5	10:13	10:15	NA	NA
Thomassen BJ 2014	1b	RCT	88	87	68.9	69.5	NA	NA	14.2	14.2
Ritter MA 1994	2b	RCT	128	123	NA	NA	NA	NA	13.0	13.1
Jones AP 2007	2b	★★★★★	53	68	70.17	70.5	27:26	21:47	13.92(0.17)	13.36(0.18)
Al-Zahid S 2012	2b	★★★★★★	33	39	NA	NA	10:23	11:28	13.55(1.47)	13.57(1.42)

LOE= Level of evidence; AD=autologous blood transfusion drainage; ND =no drainage; NA = data not available.*Mean or Mean (SD)

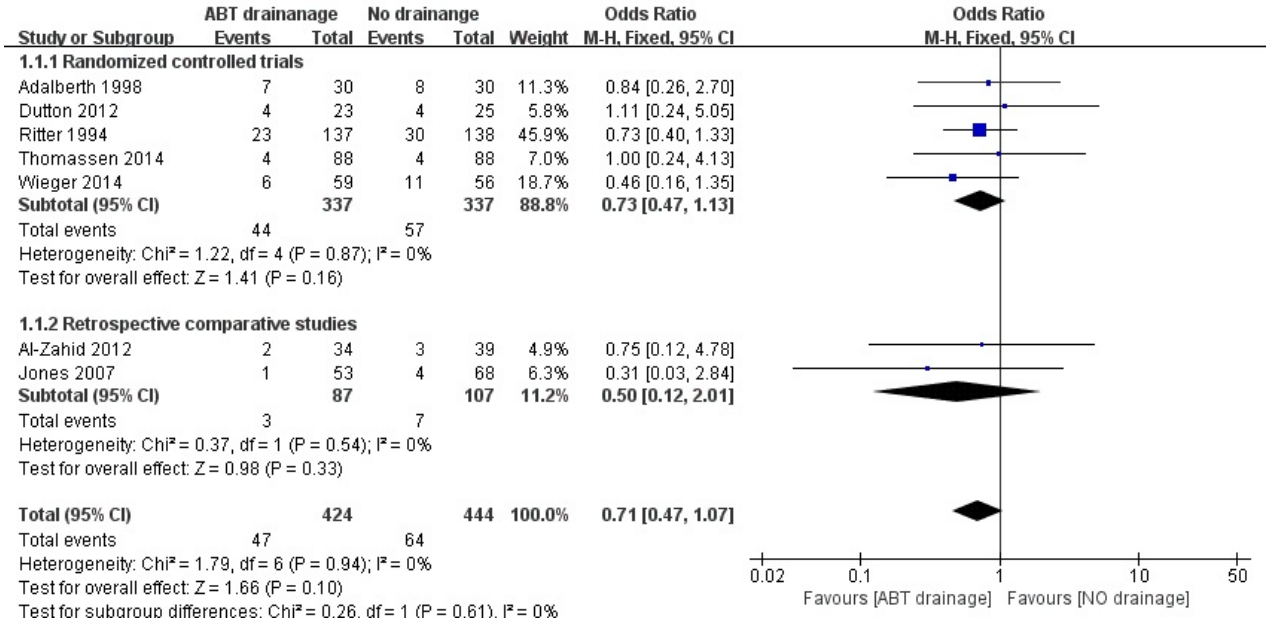

Fig. 4: Meta-analysis of the blood transfusion rates in the studies and Forest plot

reported as the mean post-operative value. The mean change in ABT drainage and no drainage groups could be obtained by subtracting the final mean from the baseline mean. A change-from-baseline standard deviations were imputed using a correlation coefficient (J and S, 2008). The Hb change from baseline was more accurate to show the benefit of ABT drainage compared to no drainage. The RCT and RCS subgroups showed substantial heterogeneity in the consistency of the trial results (chi-square =9.16, P=0.01; I^2=78%; chi-square =2.45, P=0.12; I^2=56%, respectively). Sensitivity analyses in RCT subgroup were conducted by excluding one study(Dutton *et al*., 2012) with the result showed no heterogeneity (I^2=0%, P=0.09). However no clinical diversity was identified and the result of sensitivity analyses was similar with the total analysis. We therefore used a random effects model in the statistical analysis. Subgroup pooling of data from 417 patients revealed no significant differences between the group that received ABT drainage and the group with no drainage (WMD: 0.20[-0.28, 0.68]; Z =0.82, P=0.41; WMD: 0.16 [-0.41, 0.55]; Z=0.93, P =0.35, respectively).

Range of flexion of the knee joint

Two studies (Adalberth *et al*., 1998; Ritter *et al*., 1994) reported the range of flexion of the knee joint prior to discharge. There was no heterogeneity in the consistency of results (chi-square =0.00, P=0.96; I^2=0%). When the data from 311 patients in two studies were pooled, there was no significant difference between the group that received ABT drainage and the group that did not receive drainage (WMD:-0.82 [-3.35,1.70] ; Z =0.64, P =0.52).

Wound infection

There was no significant difference between the ABT drainage and no drainage groups (3.15% and 1.45%; OR: 0.25[0.61 to 10.20]; Z=1.28, p=0.2) after the data from 396 patients in two studies (Jones *et al*., 2007; Ritter *et al*., 1994) were pooled regarding wound infection complications. No significant heterogeneity was detected (P=0.46, I^2=0%) (fig. 7). Sensitivity analysis which excluded the retrospective study (Jones *et al*., 2007) was performed. There was no change in the significance difference of the infection outcome.

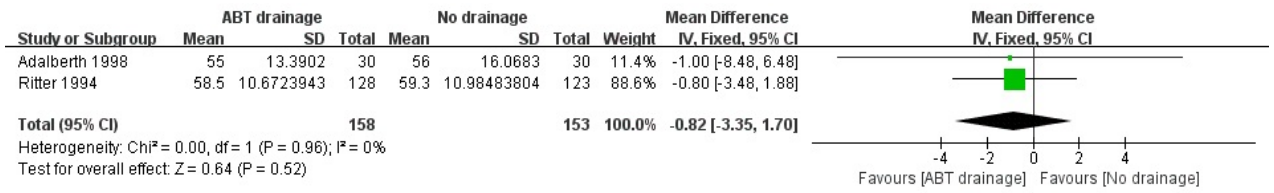

Fig. 6: Meta-analysis of the knee joint range of flexion and Forest plot

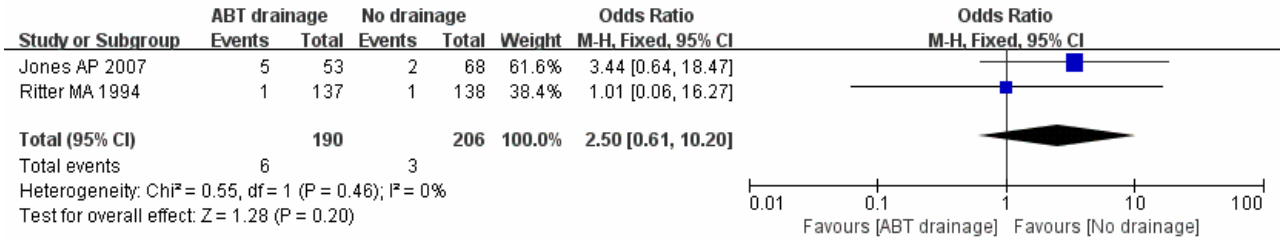

Fig. 7: Meta-analysis of wound infection and Forest plot

Publication bias

A funnel plot of the included studies that reported blood transfusion rates is shown in fig. 8. The points for all studies lie inside the 95% CI area and there is an asymmetric distribution in the vertical direction. This means that there was obvious publication bias in the analysis.

DISCUSSION

Our meta-analysis included 868 patients that participated in five RCTs and two retrospective studies that compared the efficacy of use of ABT drainage versus no drainage. The results showed no significant differences in the Hb drop compared with the mean pre-operative Hb level, the homologous blood transfusion rate, the range of knee joint flexion and post TKA surgery infection complications. Our findings do not support the routine use of postoperative ABT drains in total knee arthroplasty.

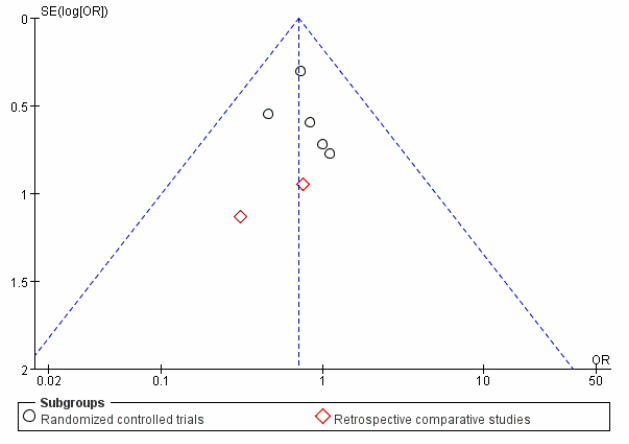

Fig. 8: Funnel plot of blood transfusion rates

Many studies have expressed considerable doubt regarding ABT drainage after TKA surgery and the concept of re-transfusing the collected blood in the drain (Esler *et al*., 2003; Holt *et al*., 1997). Contrary to the advantageous results included reducing homologous blood transfusion rate with using a ABT drainage system was shown in some studies (Carless *et al*., 2004; Muñoz *et al*., 2005; Thomas *et al*., 2001), some authors have suggested insufficient efficiency for ABT (Abuzakuk *et al*., 2007; Hansen and Hansen, 2004). In spite of the paucity of consistent evidence for their use, for many years the majority of major orthopaedic procedures were followed by the use of ABT drainage post TKA to reduce the blood transfusion rate. However, the present systematic review and meta-analysis demonstrated no significant beneficial effect of ABT drainage compared with no drainage in reducing the blood transfusion rate.

As for the secondary outcomes including Hb drop, range of flexion of the knee joint and wound infection, ABT drainage was not superior in clinical efficacy compared with no drainage in TKA. Hb drop compared postoperative Hb levels with the baseline of preoperative Hb levels was an important indicator to evaluate which way of drainage had the best clinical efficacy for TKA. According the pooled results, ABT drainage had increased wound infection rate with no statistical differences. Our systematic analysis was not sufficiently powered to provide an answer regarding ABT drainage and post-operative wound infection rates. This was due to the low incidence of wound infection and small sample size. Acting as a channel for the introduction of infection, drainage may increase infection by impairing host resistance and allowing pathogens access to a sterile field (Holt *et al*., 1997; Kim *et al*., 1998; Saleh *et al*., 2002; Zamora-Navas *et al*., 1999). Furthermore, the demands on nursing care and physiotherapy are increased to accommodate the presence of drainage. In the orthopedic surgery, wound infection is a devastating complication.

Some possible limitations of this present meta-analysis and future research directions should be pointed out. The

primary limitation is that all the selected studies were RCTs, except for two retrospective design. Subgroup and sensitivity analysis were performed to estimate the certainty degree of the result. In consideration of less number of included study, the statistical heterogeneity assessments included I^2 text were able to make false negative errors. Future systematic reviews should evaluate the indications with enough and larger multi-centre clinical literature being available. In addition, this meta-analysis limited the included articles published in English. There might be selection bias in language. Finally, no outcome measures assessed in this study are long-term measures, which is most pertinent to patients (Greidanus *et al*., 2011). Therefore, other outcomes such as range of movement, deep joint infection and component loosening, which were manifested in many years, should be considered.

CONCLUSION

We performed the first meta-analysis on studies that compared the effects of ABT drainage with no drainage with total knee arthroplasty. The pooled results indicates no efficacy of ABT drainage versus no drainage groups in terms of homologous blood transfusion rate, Hb drop compared mean pre-operative Hb levels with mean postoperative, range of flexion of the knee joint and infections after TKA surgery. Despite our use of rigorous methodology, we were unable to reach a definitive conclusion due to the inherent limitations of the eligible studies. Well-designed RCTs with large sample sizes longer term measures, and extensive follow-up period should be performed in the future to update the findings of this study.

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