

Incisional Negative Pressure Wound Therapy Dressing in Total Joint Arthroplasty: what is the evidence? A Meta-Analysis

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Research article

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Abstract

Background The purpose of this study is to evaluate whether incisional negative pressure therapy dressing (iNPWT) has an advantage over conventional wound dressing (CWD) on wound healing for patients with total joint arthroplasty (TJA)

Methods We searched the electronic databases including PubMed, The Cochrane Library, EMBASE via Ovid SP, Medline via Ovid SP, to screening published randomized controlled trials and high-quality cohort studies reported that incisional negative pressure therapy dressing applied in hip and knee arthroplasty. We analyzed the overall complications, major and minor complications, dressing changes, infection rate, and the rate of reoperation. The relevant data was analyzed by RevMan5.3.

Results Six studies met our criteria, and included 1405 incisions in 971 participants with total joint arthroplasty which were randomized either to incisional negative pressure therapy dressing group (n=578) or to conventional wound dressing group (n=827). The risk for developing a minor complication between two groups was not significantly different (risk ratio [RR] 0.58, p =0.40) and for major complication was also not significantly different (RR 0.71, p =0.39). In terms of dressing changes, the iNPWT was fewer than the control group (P <0.05). The effect of rate of infection and reoperation was not significantly different (RR 0.65, p =0.27).

Conclusions For patients underwent TJA, applying iNPWT may be associated with fewer dressing change, which maybe mean less exudation. There was no significant difference on the rate of infection and reoperation, and experiencing either minor or major complications between participants in whom iNPWT versus CWD were used for wound. However, more high-quality randomized or non-randomized controlled trials with larger sample sizes and cost-effectiveness analysis are required.

1. Background

Total joint arthroplasty (TJA) including total knee arthroplasty (TKA) and total hip arthroplasty (THA) are currently the most common surgical procedures for severe knee and hip diseases and the incidence continues to increase annually[1]. The advances in preoperative preparation, surgical techniques and postoperative care, however, often, there are some factors making the management of surgical wound challenging because of the high risk of developing complications. Importantly, the further sequelae may cause in additional surgical procedures or revisions, extension of the length of stay and an increasing economic burden substantially. Therefore, it is critical to avoid wound complications for the success of TJA.

National clinic guidelines recommend that incisions are covered with a postoperative cover dressing to help control postoperative bleeding, absorb drainage and provide mechanical protection [2]. Traditionally, conventional gauze wound dressing is regarded as postsurgical standard care. However, with higher attention to surgical wound healing, various new cover dressings emerged. Incisional negative pressure wound therapy dressing (iNPWT) has been a successful manner of wound healing management which is widely used in several surgical fields [3]. It is thought to contribute to the healing process through a number of mechanisms, including decreasing exudate, increasing blood flow, stabilization of the environment, stimulation of angiogenesis, and modulation of inflammation et al [4-8]. Although numerous studies compared the effect between iNPWT and conventional wound dressing, the preference among them remains controversial. Some studies investigated that the use of iNPWT could reduce overall incidence of complications after TJA in a comprehensive patient population [9]. However, other studies demonstrated that there was not a benefit to the use of iNPWT after TJA [10, 11].

This is the first study that assessing the effect of iNPWT on wound healing after TJA systematically. The purpose of our study is to analyze the included studies to compare (1) the rate of overall, minor and major complications, (2) the rate of infection, (3) the rate of reoperation, and (4) the dressing changes between iNPWT group and CWD group after TJA.

2. Methods

The methods we used were based on the recommended PRISMA checklist guidelines [12]. This study was a meta-analysis, so there were no conflict of interests and ethical approval.

2.1. Search Strategy

We searched relevant studies by June 3rd, 2019 in the following databases: PubMed, Medline via Ovid SP, EMBASE via Ovid SP, and The Cochrane Library. Only English language publications were included in our meta-analysis. Search strategy we adopted in above databases as follows: (Negative-Pressure Wound Therapy OR negative pressure wound therapy OR vacuum assisted closure OR topical negative pressure therapy) AND (total knee arthroplasty OR total hip arthroplasty OR total knee replacement OR total hip replacement OR TKA OR THA OR TKR OR THR).

2.2. Outcome Measures

The primary outcomes in this study were complications including overall, minor and major complications, dressing changes. Furthermore, we also took the rate of infection and reoperation as the secondary outcomes between the two groups. For complications, we defined it as minor (blisters, superficial infection, exudation, hematoma, seroma, swelling, or other) or major (deep infection, wound dehiscence) for each individual study[13].

2.3. Criteria for Including Studies

The included studies met PICOS (patients, intervention, comparator, outcome, study design) criteria. These criteria were as follows: (1) Participants received TKA or THA; (2) The intervention was applying iNPWT for TJA; (3) The comparator was applying CWD for TJA; (4) The outcomes of included studies with adequate reported data; (5) The study designs were randomized controlled trials (RCTs) or prospective cohort studies (PCS).

2.4. Data Extraction

Two authors screened the studies independently. Initially, titles and abstracts were assessed to search potential studies, then obtaining and screening the full text of potentially relevant publications. Once there were any disparities, we resolved it by discussion. A third author was consulted if necessary.

Two authors independently extracted outcomes of the eligibility studies in pre-designed data collection form. The following information and data were extracted: study characteristics included first author, year of publication, settings and participants characteristics (such as age, sex, BMI, surgery type); study design characteristics included method of randomization, blinding, assessment of selective reporting; incomplete data and funding sources; outcomes included definition of outcomes and numerical data. Any discrepancy was resolved by a third author.

2.5. Assessment of Risk of Bias in Included Studies

The quality of included studies was assessed independently by 2 authors. We made risk of bias judgment based on tools described in the Cochrane Handbook [14]. Seven domains included random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias were considered to be an evaluation indicator. The overall risk of bias in included trials was evaluated as low risk of bias, high risk of bias and unclear risk of bias. Additionally, we used Jadad scales to evaluate the risk of bias for RCTs. For prospective cohort studies, we assessed the risk of bias by Newcastle-Ottawa scale. The study was assessed as high quality when the Jadad score was more than 4 points. As for Newcastle-Ottawa scale, a high quality study obtained a score of more than 5 points [15, 16].

2.6. Data Synthesis

The statistical analysis of overall included studies was performed by RevMan5.3 (Cochrane Collaboration). We used risk ratios (RR) and its 95% confidence interval (CI) to measure the dichotomous outcome data, such as occurrence of complication and infection et al. For continuous outcome data such as the number of dressing change, we used the measure of mean differences (MD) and its 95% confidence interval (CI). Heterogeneity in synthetic results was usually caused by clinical and methodological heterogeneity. We used the chi-squared test and I^2 statistic to assess statistical heterogeneity. According to statistical heterogeneity, we selected the fixed-effects model if the I^2 estimated $\leq 50\%$ accompanied by a statistically significant chi-squared ($P < 0.1$). When there was heterogeneity, we sought the sources of it. If the source was ascertained, we intended to perform further subgroup analysis. Otherwise, we analyzed the data in a random-effects model.

Funnel plot we adopted for this study to test the reporting bias when the number of included trials were >10 [14].

3. Results

3.1. Literature Screening

The literature search initially identified 135 studies. 68 studies were screened after removing the duplicates and 54 studies were excluded by screening the titles and abstracts. Eight of 14 full-text articles were excluded through careful check. Two studies were excluded due to inadequate outcome reporting. One study was not eligible because of not comparing iNPWT with conventional wound dressing. 5 studies were not completed and published. Finally, 6 studies were included in this study (Fig.1). Among them, there were 5 RCTs and 1 prospective cohort study.

3.2. Study Characteristics

Six studies with 1405 incisions in 971 participants with total joint arthroplasty were included [9, 10, 17-20]. Howell et al [18], investigated 51 patients underwent 60 TKA surgeries. Manoharan et al [10], reported not all participants randomized allocated. Twenty-one patients with 42 postoperative knee randomized into two group. The included participants' type of surgery was as followed: TKA, THA. All studies compared incisional negative pressure wound therapy dressing with conventional wound dressing. The age of most of participants >45 years old (average age range: 66-80 years old). The BMI of most of participants >27 kg/cm². The details of study characteristics were shown in Table 1.

3.3. Risk of Bias

Three studies of the 5 included studies [10, 18, 19] performing adequate method of randomization and allocation concealment were considered as low risk of bias. The randomization and allocation concealment were using sealed opaque envelopes or an online computer software. Another 2 studies [17, 20] did not state the randomization. One study [17] reported that a single-blind method was used. One trial [19] reported that used non-blind method. Another 3 studies [10, 18, 20] did not report blinding procedures. But we were inclined to think that the patients and outcome estimator were not blinded, which did not influence the outcome evaluation because of objective measurements. That one study [18] reported incomplete

outcome data resulted from stopped prematurely due to complications, so it was considered as high risk of bias due to selective reporting. The risk of bias assessment of included studies was shown in Fig 2. Publication bias was assessed by funnel plot diagram (Fig 3). The funnel plot diagrams of overall complications, minor and major complications, the rate of infection and reoperation were symmetrical, which indicated a low risk of publication bias. We failed to evaluate the risk of publication bias of the number of dressing changes due to only 2 studies reported it.

3.4. Outcome Measures

3.4.1. Overall Complications

The various complications reported by these original studies included blistering, exudate, superficial and deep surgical site infection et al. Result from this meta-analysis supported that there was no significant difference in rate of overall complications between iNPWT group and control group (RR=0.90, 95% CI 0.32-2.57, $p=0.53$, Fig. 4).

3.4.2. Minor and Major Complications

The detail of minor and major complications was shown in Table 2. In terms of minor complications, there was no significant difference between 2 groups (OR=0.58, 95% CI 0.13-2.61, $p=0.48$; Fig.5). Similarly, in terms of major complications, result from this study demonstrated that there was no significant difference between 2 groups (OR=0.71, 95% CI 0.33-1.53, $p=0.38$; Fig.6).

3.4.3. Dressing Changes

Two studies [17, 19] measured the number of the dressing changes. Applying incisional negative pressure wound therapy dressing resulted in fewer dressing changes than conventional wound dressing (MD=-2.00, 95% CI -2.24 - -1.76, $p<0.05$, Fig. 7).

3.4.4. Infection Rate

Three studies [9, 18, 20] reported the infective events included superficial and deep infection. One study [20] found there was a significant higher rate in late infection after TKA compared with THA (6.1% vs 0.9%, $P=0.03$). However, there was no clear statistical difference between iNPWT group and control group. Redfern et al [9], reported that the overall rate of infection decreased significantly in iNPWT group compared with control. As for pooled data, there was also no significant difference between the two groups (RR=0.65, 95% CI 0.30-1.40, $p=0.27$, Fig. 8).

3.4.5. Rates of Reoperation

Four studies [9, 18-20] reported the reoperation. Redfern et al [9], reported that the number of patients who required reoperation due to complications in each of groups were 3 and 15. Howell et al [18], reported that one patient in each of the two groups had surgical treatment postoperatively due to deep surgical site infection. Karlakki et al [19], informed of three participants in control group that required surgical treatment again because of postoperative complications. Keeney et al [20], reported that the rates of reoperation in each of groups were 3/185 and 6/213. However, the pooled data did not show significant difference between groups. (RR=0.46, 95% CI 0.20-1.03, $p=0.06$, Fig. 9).

4. Discussion

Various strategies of preventing wound complications have already been developed, and the core goal of these strategies is to improve the prognosis and survival qualities of patients with TJA. However, the effect of application of diverse wound dressings remain unclear. Some present studies found that iNPWT has an advantage on wound healing [5, 21]. A previous systematic review [22] evaluating the prophylactic use of iNPWT for wound complications in several surgical fields such as laparotomy for abdominal, coronary arteries bypass grafting, and lymphadenectomy. It considered that incisional negative pressure wound therapy dressing seemed to be an effective prophylactic measure in decreasing complications and reoperation rate and be regarded as potentially cost saving especially in high-risk patients. However, there was limited studies on the application of iNPWT in orthopedic surgery. Newman et al [21] conducted a RCT on application of iNPWT compared with silver-impregnated occlusive dressing for revision total hip or knee arthroplasty in patients at high risk for infection. This study found that iNPWT may decrease the rate of postoperative wound complications. Pachowsky et al [23] conducted a RCT about the influence of iNPWT on the development of postoperative seromas in the wound area. The results of this RCT demonstrated that iNPWT may decrease development of postoperative seromas. One cost-effectiveness analysis [24] of iNPWT on primary hip and knee replacements showed that the efficacy of iNPWT in terms of improving cost-effectiveness and comfort for both patients and caregivers was irrefutable. One retrospective study reported that there was significant difference in overall complications between iNPWT and conventional wound dressing. However, the finding was not statistically significant when each individual complication was compared separately[25]. Another study found that iNPWT may increase the Occurrence of blisters, which resulted from trial stopping prematurely [18]. Gillespie et al [11] reported a RCT on iNPWT compared with hydrocolloid dressing for patients undergoing THA. This study found that the iNPWT patients had less surgical site infection indicators but experienced more other postoperative complications and its costs were higher. A systematic review, karlakki et al [26] demonstrated 9 studies reporting the application of iNPWT in orthopedic surgery, five of which were randomized controlled trials (RCTs). Only 3 RCTs involve either THA or TKA. Therefore, there was a lack of high-level evidence in the field of adult arthroplasty concerning the application of iNPWT. The benefit of iNPWT after TJA was uncertain.

This meta-analysis including 5 RCTs and 1 prospective cohort study aims to evaluate whether there is difference between iNPWT and conventional wound dressing on wound healing in patients who received TJA. Results from this study showed that applying incisional negative pressure wound therapy dressing may decrease the postoperative dressing changes. It seems to demonstrate that iNPWT may reduce the drainage. One of these studies reported that conventional wound dressing was changed depending on the wound leakage, and iNPWT changed when the dressing was completely soaked with fluids. The other study defined criteria of dressing change as exudate filling more than 50% of dressing. The outcomes may be potentially different biased due to the difference of the criteria for dressing change. Therefore, more pertinent studies are required.

The complications including overall, minor and major were the primary outcome in our study. The occurrence of complications was a sign of wound status, even result in failure of surgery. Our meta-analysis defined complication as minor or major. Some studies indicated that iNPWT had an effect on decreasing complications but there were some studies reporting the opposite efficacy[18, 21, 23]. In this meta-analysis, no difference in overall, minor and major complications were found after TJA.

The rate of infection was also an important outcome in this study. Severe infection was associated with adverse effects including failure of surgery, difficulty of wound healing, and cost. Hence, infection control was desirable. Previous study reported that the iNPWT had less surgery site infection[23]. This was consistent with our study but these differences were no statistically significantly different. Because of the limitations of the results available in the included studies, the lack of diagnosis of infection may cause the result to be biased.

With regard to the rate of reoperation, in our meta-analysis, four included studies reported that the rate of reoperation in iNPWT group was lower[9, 18-20]. However, there were no statistically significant difference. In addition, two included study reported that the reduction in the length of the stay for application of iNPWT, although measurable, was not statistically significant difference.

The limitations of this meta-analysis included that: firstly, there was selection bias in studies (2/5), which did not state the method of randomization. The potential bias of selective reporting due to the stopped prematurely might also influence the true effect measurement. Secondly, one study involving the patients who underwent revision THA or TKA was included. This study excluded the patients who diagnosed as periprosthetic fracture or prosthetic joint infection and accepted antibiotic therapy within the past month. However, which also could influence the results. Thirdly, the number of included studies and sample sizes in this meta-analysis was small, which may lead to an imprecise effect estimation. Finally, subgroup analysis could not be performed for any source of heterogeneity due to the limitations of the results available in the included studies, which may impact the true effect of clinical outcomes.

5. Conclusions

For patients with TJA, compared with conventional wound dressing, incisional negative pressure wound therapy dressing may reduce the dressing changes postoperatively. The effect of incisional negative pressure wound therapy dressing on the complications, blistering, reoperation, and infection were uncertain. The effect of incisional negative pressure wound therapy dressing on the length of hospitalization and mortality remains unclear due to insufficient data. Besides, the more expensive cost of incisional negative pressure wound therapy dressing may increase patients' economic burden.

This meta-analysis showed that the current evidence comparing the advantage of these 2 types of dressing is still limited. More prospective randomized controlled trials with high quality are required.

Abbreviations

iNPWT, incisional negative pressure therapy dressing; CWD, conventional wound dressing; TJA, total joint arthroplasty; RR, risk ratio; TKA, total knee arthroplasty; THA, total hip arthroplasty; RCTs, randomized controlled trials; PCS, prospective cohort studies; BMI, body mass index; CI, confidence interval; MD, mean differences.

Declarations

Ethics approval

Ethical approval is not necessary because it is a comment on previously published articles and does not involve the handling of any personal patient data.

Consent to publication

Not applicable

Availability of data and materials

All data and materials are contained within the manuscript

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

The following authors designed the study (BS), gathered the data (WXW, MYL), analyzed the data (WXW, YL), wrote the initial drafts (WXW), and ensured the accuracy of the data and analysis (BS, YZ, YGW). All authors have read and approved the manuscript

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Tables

Study ID	Participants					Intervention (I/C)	Reference type	QAS	Outcomes
	N (I/C)	Age (years) (I/C)	Sex (M/F)	BMI (kg/cm ²) (I/C)	Type of surgery				
Giannini 2018 [17]	100 (50/50)	66.0/66.8	37/63	27.7/28.2	Revision THA or TKA	iNPWT ^a /CWD	RCT	4	ASEPSIS score, Blisters, VAS, Dressing changes
Howell 2011 [18]	60 (24/36)	Unclear	Unclear	> 30	TKA	iNPWT ^b /CWD	RCT	6	Infection rate, Blisters,
Karlakki 2016 [19]	209 (102/107)	69.0/69.2	104/105	30.1/28.4	THA or TKA	iNPWT/CWD	RCT	5	Length of stay, Wound complications, Dressing changes, Cost- effectiveness
Keeney 2019 [20]	398 (185/213)	60.6/ 60.5	164/234	34.6/ 36.5	THA or TKA	iNPWT ^a /CWD	RCT	4	VAS, Wound complications, Wound drainage, Late infection rate
Manoharan 2016 [10]	42 (21/21)	Unclear	19/14	Unclear	TKA	iNPWT ^b /CWD	RCT	6	Cost of dressings, Wound complications, QoL factors, Maceration, Blisters.
Redfern 2017 [9]	596 (196/400)	66.9/66.8	251/345	30.5/30.9	THA or TKA	iNPWT/CWD	PCS	7	Wound complications, Infection rate
The detailed study characteristics of included trials									
N, the number of incisions; I, intervention group; C, control group; BMI, body mass index; iNPWT, incisional negative pressure wound therapy dressing; CWD, conventional wound dressing; TKA, total knee arthroplasty; THA, total hip arthroplasty; RCT, randomized controlled trials; PCS, prospective cohort studies ; ASEPSIS, additional treatment, the presence of serous discharge, erythema, purulent exudate, and separation of the deep tissues, the isolation of bacteria, and the duration of inpatient stay; VAS, visual analogue score; QoL, quality of life.									
^a the negative pressure value is 80 mmHg sub-atmospheric; ^b the negative pressure value is 125 mmHg sub-atmospheric.									

Table 1

Table 2 Complications

	Study ID	Minor			Major		Total participants with complications
		Blisters	Superficial infections	Minor, other	Deep infections	Major, other	
iNPWT group	Giannini 2018 [17]	6	0	0	0	0	6
	Howell 2011 [18]	15	0	0	1	0	15
	Karlakki 2016 [19]	0	0	2	0	0	2
	Keeney 2019 [20]	0	1	15	6	0	22
	Manoharan 2016 [10]	1	0	0	0	0	1
	Redfern 2017 [9]	0	0	0	2	1	3
Control group	Giannini 2018 [17]	15	0	0	0	0	15
	Howell 2011 [18]	3	0	0	1	0	4
	Karlakki 2016 [19]	0	5	4	0	0	9
	Keeney 2019 [20]	0	4	19	4	0	27
	Manoharan 2016 [10]	0	0	1	0	0	1
	Redfern 2017 [9]	0	9	51	5	13	22

Figures

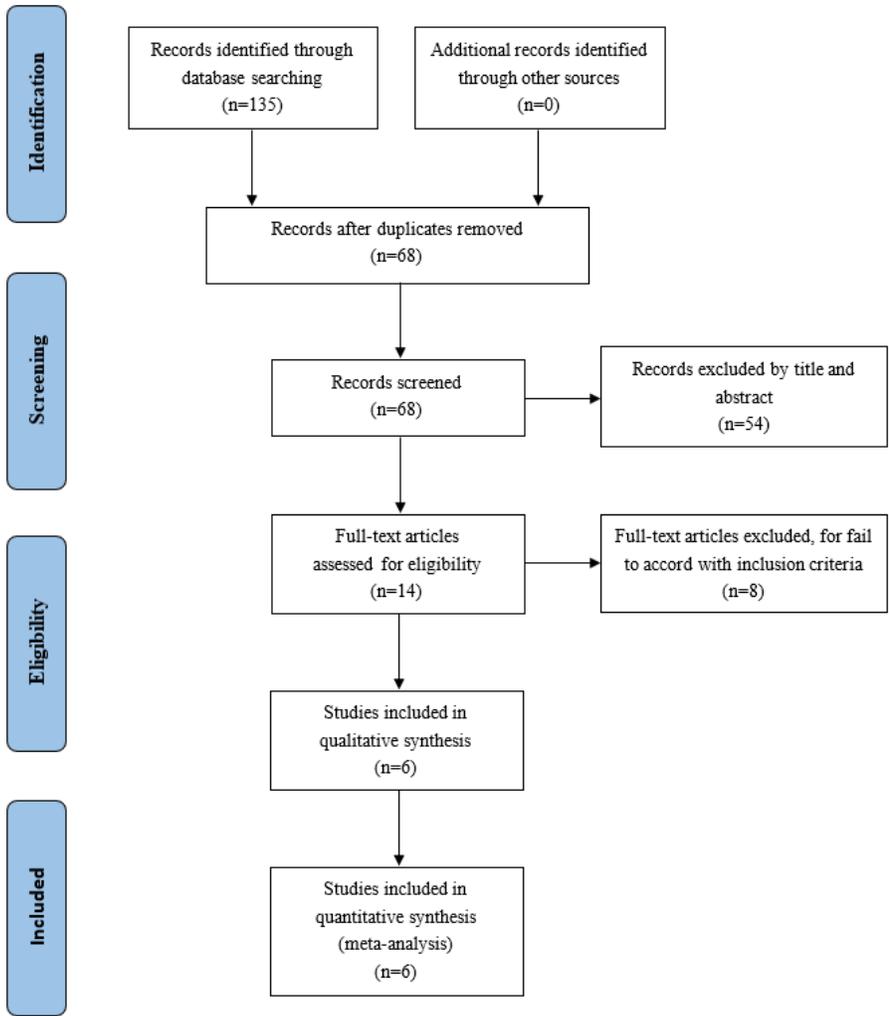


Figure 1
Flowchart of inclusion and exclusion for eligible studies.

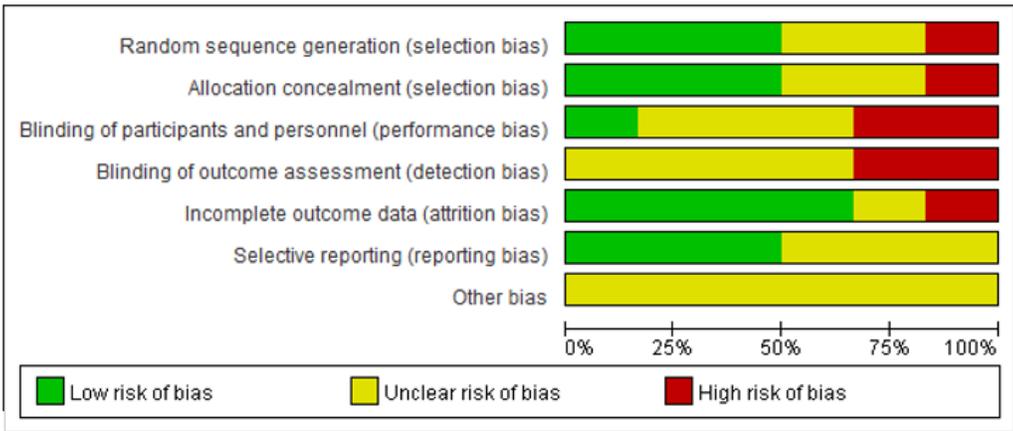


Figure 2
Risk of bias assessment of included studies.

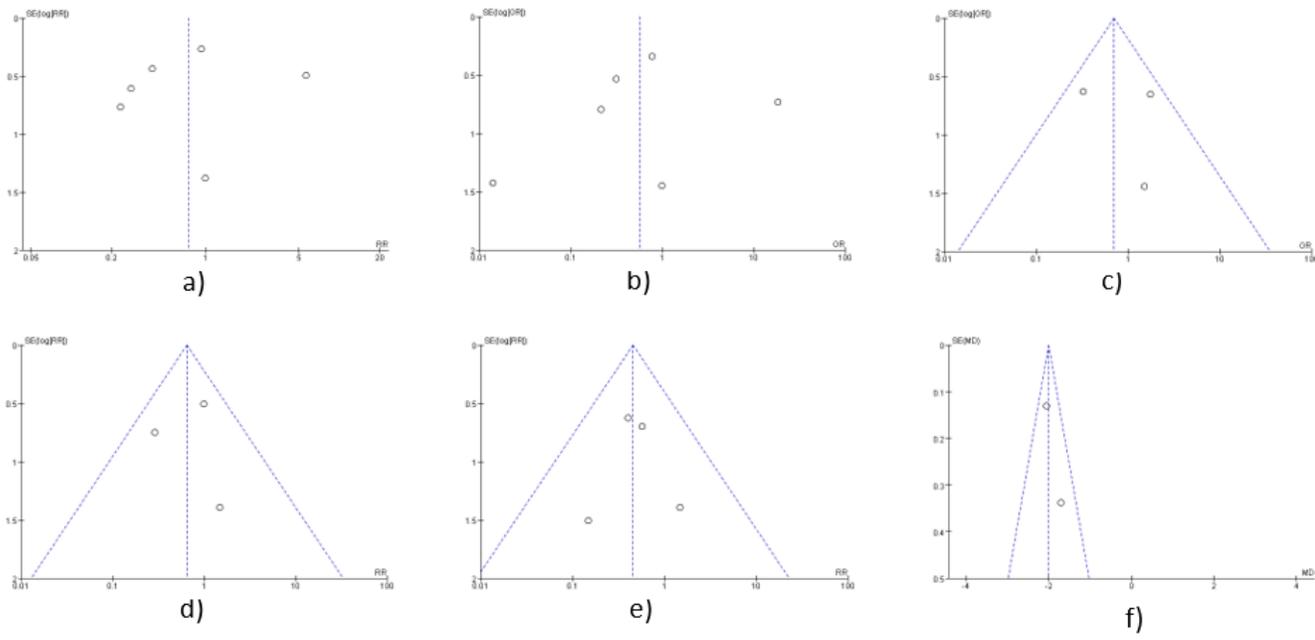


Figure 3
 Funnel plot. (a) A funnel plot of overall complications; (b) A funnel plot of minor complications; (c) A funnel plot of major complications; (d) A funnel plot of the rate of infection; (e) A funnel plot of the rate of reoperation; (f) A funnel plot of the number of dressing changes.

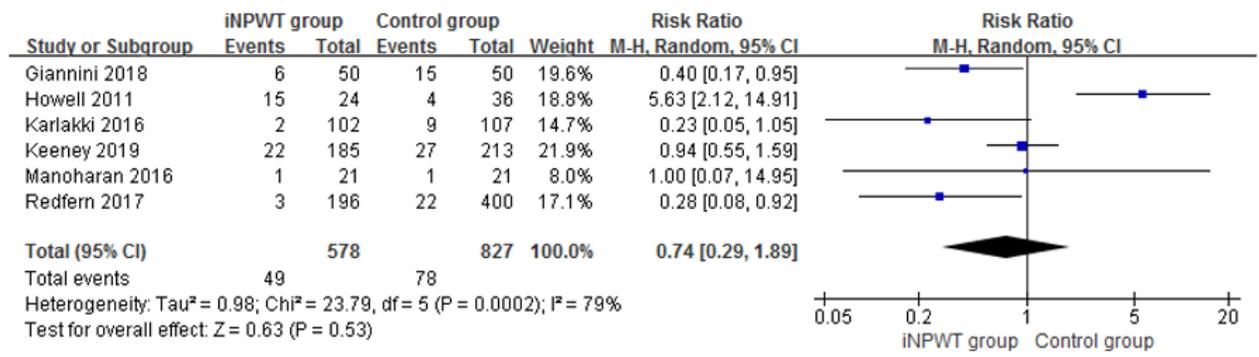


Figure 4
 The overall complications forest plot analysis.

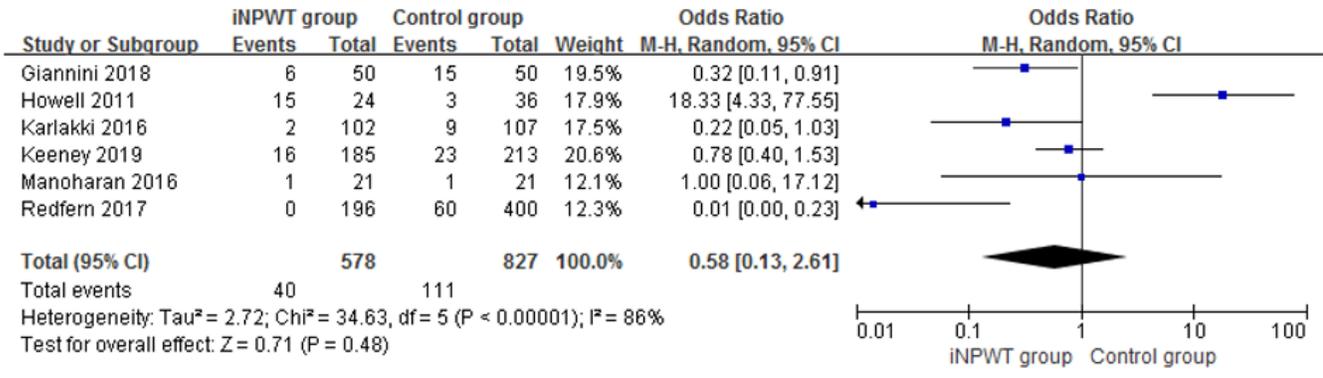


Figure 5

The minor complications forest plot analysis.

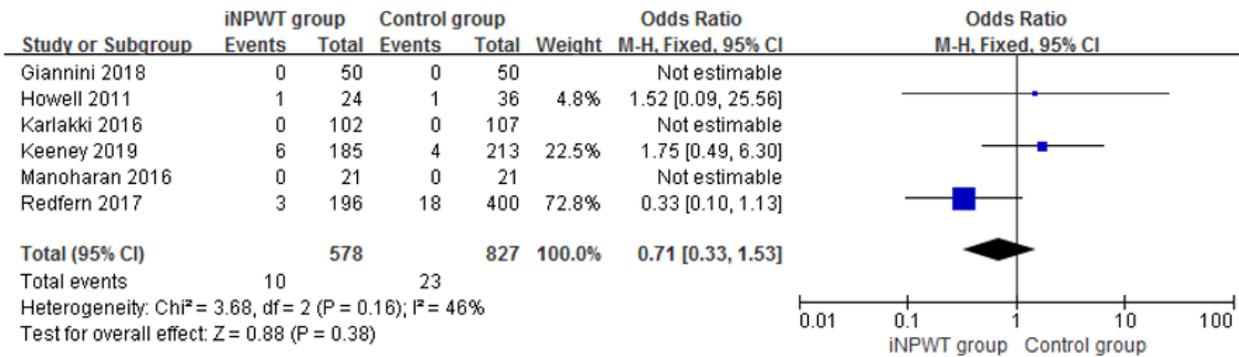


Figure 6

The major complications forest plot analysis.

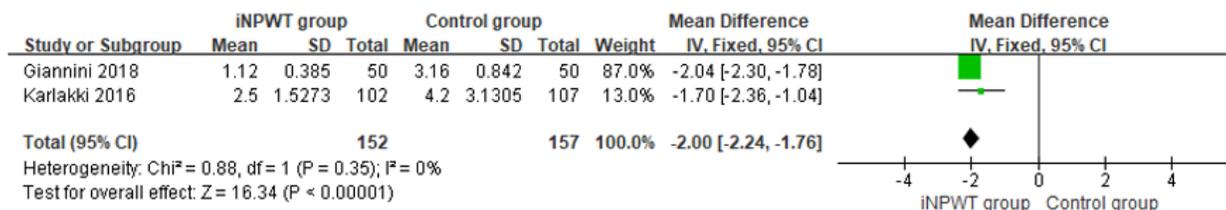


Figure 7

The dressing changes forest plot analysis.



Figure 8

The rate of infection forest plot analysis.

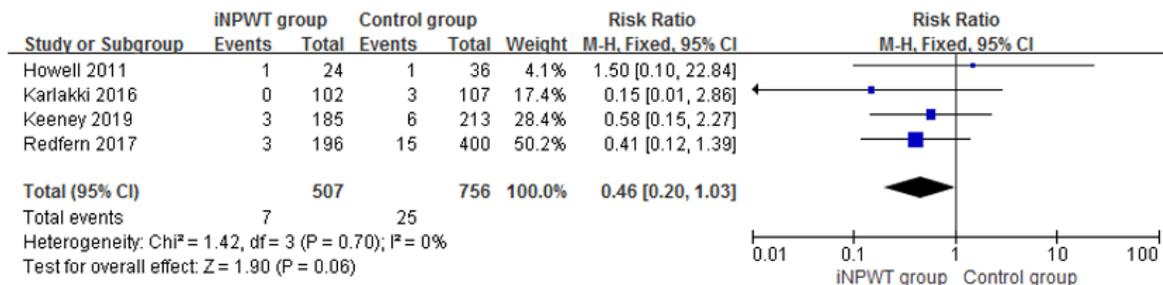


Figure 9

The rates of reoperation forest plot analysis.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [PRISMAchecklist.doc](#)