

Original Article

The incidence of and risk factors for deep infection after primary shoulder arthroplasty: an updated systematic review and meta-analysis

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Abstract: Background and aims: This study aims to investigate the incidence of and risk factors associated with deep infection after primary shoulder arthroplasty. Methods: Computerized and additional manual searches were performed in Medline, Embase, CNKI (Chinese National Knowledge Infrastructure), and the Cochrane central database through October 2017 for potential studies. Studies meeting the quality assessment criteria of the Newcastle-Ottawa Scale and evaluating the risk factors for deep infection after primary shoulder arthroplasty were recognized as eligible and included in this study. Two reviewers independently extracted the relevant data and resolved any disagreement by discussion and consensus. Stata 12.0 was used to perform all the statistical analyses. Results: Seven studies met the quality assessment and were included in this study. There were a total of 493,148 cases of primary shoulder arthroplasty and 1,314 cases of deep infection, indicating an incidence of 0.3%. Several significant risk factors associated with deep infection after primary shoulder arthroplasty were identified, including male gender (OR, 1.79; 95% CI, 1.23-2.60), avascular necrosis (OR, 2.64; 95% CI, 1.61-4.34), rotator cuff arthropathy (OR, 2.14; 95% CI, 1.55-2.95), proximal humerus fracture (OR, 2.68; 95% CI, 1.93-3.73), nonunion of humerus fracture (OR, 5.32; 95% CI, 3.52-8.02). Conclusions: Surgeons should pay close attention to patients with the above-mentioned medical conditions in order to reduce deep infection after primary shoulder arthroplasty.

Keywords: Deep infection, shoulder arthroplasty, incidence, risk factors

Introduction

Shoulder arthroplasty is a common surgical treatment for various comorbidities involving the glenohumeral joint, such as arthritis, rotator cuff disease, trauma, and tumors. Postoperative deep infection, although rare, can have severe consequences, such as disability, implant failure, and occasionally, septicemia. In the literature, the rate of deep infection is reported to be 0.4% to 2.9% after total shoulder arthroplasty (TSA) [1, 2], 3.3% to 5.0% after reverse total shoulder arthroplasty (RTSA) [3, 4] and 1.0% after hemiarthroplasty (HSA) [5].

The identification of preoperative and intraoperative risk factors and the implementation of targeted preventive measures for those patients at high-risk of postoperative deep in-

fection is of important clinical significance in the reduction and even avoidance of its occurrence. Previous epidemiological studies have investigated and assessed the risk factors associated with shoulder arthroplasty infection, such as rheumatoid arthritis, obesity, and the revision of a prior failed arthroplasty [6-8]. However, some limitations exist in these individual studies, including a small sample size, single-center institution, and the inclusion of a single or very few potential risk factors. Furthermore, most of these risk factors were obtained through univariate analysis, which might be compromised by the residual confounding effects or an inconsistent definition of postoperative infection. Therefore, it remains uncertain whether these previously identified factors from individual studies can predict deep infection after shoulder arthroplasty.

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Up to now, no quantitative comprehensive study has been made to summarize these risk factors about this critical issue. Given that, we conducted the present meta-analysis analysis, using data available from previous original studies, to summarize these risk factors in the expectation of aiding clinicians in the determination of which patients are at risk of infection after shoulder arthroplasty.

Methods

Literature search

A computerized search was performed on Medline, Embase, CNKI (Chinese National Knowledge Infrastructure), and the Cochrane central database (for articles published through October 2017) for studies exploring risk factors for deep infection after shoulder arthroplasty. We used the following search terms and Boolean operators: “deep infection” or “surgical site infection” or “prosthetic infection” or “SSI” or “PJI” or “prosthetic joint infection” and “TSA” or “RTSA” or “HSA” or “total shoulder arthroplasty” or “reverse total shoulder arthroplasty” or “hemiarthroplasty”. Meanwhile, an additional manual search of references in the identified papers and systematic reviews was performed for possible inclusion.

Two reviewers (Chen and Liu) independently evaluated the titles and abstracts of the identified studies. Only full-text studies without language restriction were included in this meta-analysis. The inclusion criteria were as follows: (1) a study of cohort, observational or randomized controlled trials was performed to explore the risk factors for infection after shoulder arthroplasty; (2) case was defined as the presence of deep infection after shoulder arthroplasty, and control was defined as the absence of deep infection; (3) sufficient data were published for estimating an odds ratio (OR) or hazard ratio (HR) with 95% confidence intervals (CIs).

Quality of included studies

The quality of the included studies was evaluated using the Newcastle-Ottawa Scale (NOS) [9]: based on three main factors: the selection of the study groups (0-4 points), the comparability of the groups (0-2 points), and the determination of either the exposure or the outcome

of interest (0-3 points), with a perfect score of 9 and the worst of 0.

Data extraction

All the data were carefully extracted from all eligible articles independently by the two reviewers (Chen and Liu). The following variables were extracted from each study: first author, publication year, country, significant risk factors, definitions, and numbers of presence and absence of infection after shoulder arthroplasty, and numbers of citations for each potential risk factor for infection. Because of the discrimination of the definition of deep infection in different articles, studies included in our review could be separated into PJI (prosthetic joint infection), deep infection and SSI (surgical site infection). We accepted the original diagnosis of PJI, deep infection and SSI in the original studies, based on the clinical manifestations or bacterial culture. Any disagreements were resolved by discussion and consensus.

Statistical analyses

For each risk factor, we tried to extract the adjusted OR (from the multivariate analysis model) with its 95% CI in the original study. When the adjusted OR was not provided, we computed crude ORs based on the given frequency. Then, the abstracted ORs were pooled across the studies to assess the associations between the different variables and the risk of infection with a $P < 0.05$ indicating a significant difference. Heterogeneity between the studies was qualitatively tested by Q-test statistics with the significance set at $P < 0.10$ [10]. The I^2 statistic was used as a quantitative measure of heterogeneity, with an I^2 more than 50% indicating a significant inconsistency. A random effects model was adopted to calculate pooled ORs in the case of significant heterogeneity ($P < 0.10$ or $I^2 > 50\%$); otherwise, a fixed-effects model was used. The meta-analyses of the significant risk factors were summarized graphically using a forest plot. Publication bias was assessed by Begg's test and graphed by a funnel plot, and a $P < 0.10$ was considered significant. Furthermore, to explore sources of heterogeneity, a sensitivity analysis was performed for certain risk factors according to the following factors: inclusion criteria, lower methodological quality of included studies, the larger size of the confidence interval, and other ele-

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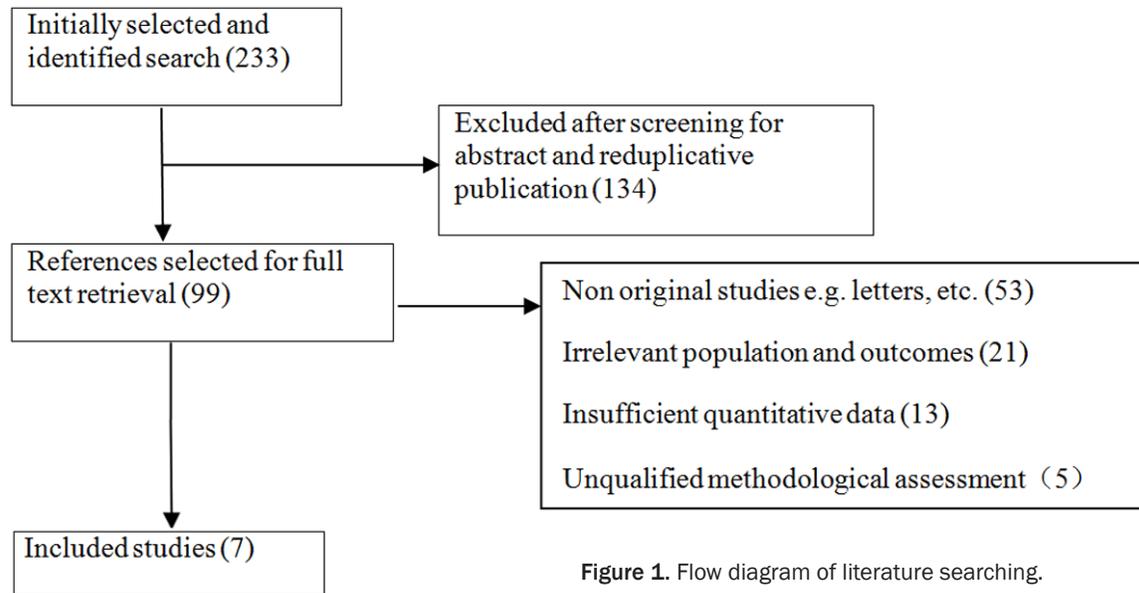


Figure 1. Flow diagram of literature searching.

Table 1. The detailed information for the characteristics of the 7 eligible studies

Author	Publication	Country	Study design	NOS score	Non-infection group	Infection group	Total	Age (y)	Significant factors
Singh	2012	USA	Prospective	8	1417	14	1431	63±16	Trauma
Singh	2012	USA	Prospective	8	2556	32	2588	65±12	Male gender and younger age
Richards	2014	USA	Retrospective	8	4483	45	4528	69.7±10.3	Male
Morris	2015	USA	Prospective	8	286	15	301	68.3±11.3	History of a prior failed arthroplasty and age younger than 65 years
Smucny	2015	USA	Retrospective	8	400604	384	400988	NA	Medicaid insurance, fracture nonunion, avascular necrosis, proximal humeral fracture, comorbidities, in-hospital events, and increased duration of hospital stay
Padegimas	2015	USA	Retrospective	8	81690	808	82498	NA	Male gender, younger age, preoperative anemia, drug abuse, and recent weight loss/nutritional deficiency
Florschütz	2015	USA	Retrospective	7	798	16	814	65±13	Previous nonarthroplasty operative history

ments. All analyses were performed using the software Stata 11.0 (Stata Corporation, College Station, TX).

Results

Characteristics of identified studies

The initial search yielded 233 relevant publications, of which 226 were excluded for reproduction studies and miscellaneous reasons (re-

views, letters, or not relevant to our study) on the basis of the title/abstract and full text (**Figure 1**). The remaining 7 studies were included in the final analysis [4, 5, 11-15]. All of them were published in English and all were published after 2012. These 7 studies altogether included 493,148 patients treated with primary shoulder arthroplasty. There was a total of 1,314 cases of infection, suggesting an accumulated incidence of 0.3% (1314/493148). The rate of deep infection was 1.1% after TSA,

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Table 2. Detailed data on 11 potential risk factors for the infections and the outcomes of meta-analysis

Potential risk	No of studies	Pooled OR	LL 95% CI	UL 95% CI	P value	Q-test (P)	I^2 (%)
Male	7	1.79	1.23	2.60	0.002 ^b	<0.001	79.7
Age, per 1-year increase	3	0.97	0.94	1	0.045 ^b	0.012	77.3
BMI>30	4	0.97	0.65	1.46	0.891 ^a	0.588	0
DM	3	1.18	0.94	1.48	0.143 ^a	0.969	0
RA	3	1.57	0.73	3.35	0.245 ^a	0.690	0
IA	2	2.17	0.49	9.59	0.305 ^a	0.988	0
ASA	3	0.86	0.51	1.47	0.582 ^a	0.457	0
RCA	2	2.14	1.55	2.95	<0.001 ^a	0.602	0
Avascular necrosis	2	2.64	1.61	4.34	<0.001 ^a	0.693	0
Proximal humerus fracture	2	2.68	1.93	3.73	<0.001 ^a	0.366	0
Nonunion of humerus fracture	2	5.32	3.52	8.02	<0.001 ^a	0.166	47.9

OR, odds ratio; LL, lower limit; UL, upper limit; DM, diabetes mellitus; BMI, body mass index; RA, rheumatoid arthritis; IA, instability arthritis; RCA, Rotator cuff arthropathy; ASA, American Society for Anesthesiologists. ^aFixed-effects model was performed. ^bRandom-effects model was performed. I^2 statistic was defined as the proportion of heterogeneity not due to chance or random error.

2.8% after RTSA, and 1.0% in the HSA cases, respectively. Detailed information about these included studies is shown in **Table 1**.

The outcome of the quality assessment for these studies is as follows: six studies scored 8 [4, 5, 11-14]; one study scored 7 [15].

A meta-analysis of combinable data was conducted to analyze the risk factors for infection after primary shoulder arthroplasty, and the main results are summarized in **Table 2**. The combined odds ratios ranged from 0.86 to 5.32. Significant heterogeneity was observed among the studies when evaluating the potential risk factors including male gender and age. On the basis of the combined ORs and 95% CI, the significant risk factors were male gender (OR, 1.79; 95% CI, 1.23-2.60), avascular necrosis (OR, 2.64; 95% CI, 1.61-4.34), rotator cuff arthropathy (OR, 2.14; 95% CI, 1.55-2.95), proximal humerus fracture (OR, 2.68; 95% CI, 1.93-3.73), nonunion of humerus fracture (OR, 5.32; 95% CI, 3.52-8.02). Increasing age was associated with a decreased likelihood for the development of an infection (OR, 0.97; 95% CI, 0.94-1). The outcome of the analyses for some variables mentioned above as significant risks are presented as forest plots (**Figure 2**). The other variables, including BMI, diabetes mellitus, rheumatoid arthritis, instability arthritis, and ASA score, were not identified as risk factors for infection after shoulder arthroplasty ($P>0.05$). Begg's funnel plot for publication

bias (with 95% pseudo confidence limits) showed a non-significant result for sex differences between infection and non-infection after primary shoulder arthroplasty ($P=0.548$) (**Figure 3**).

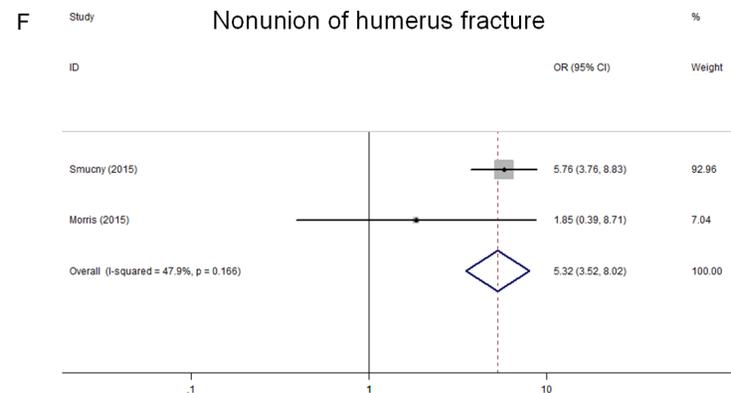
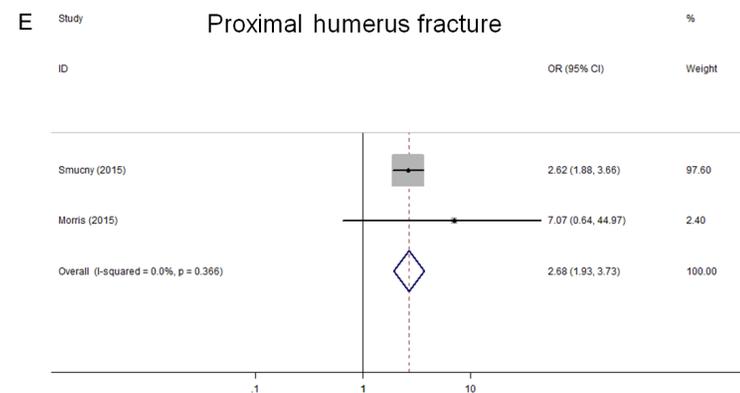
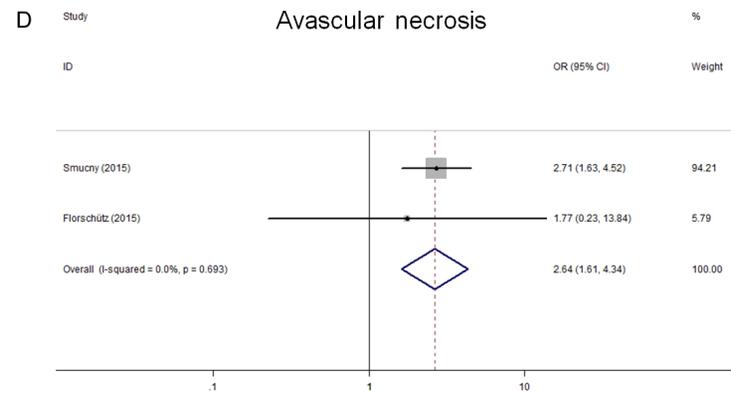
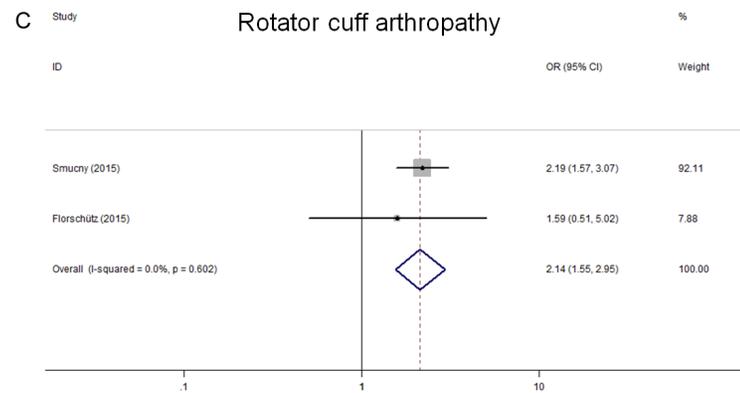
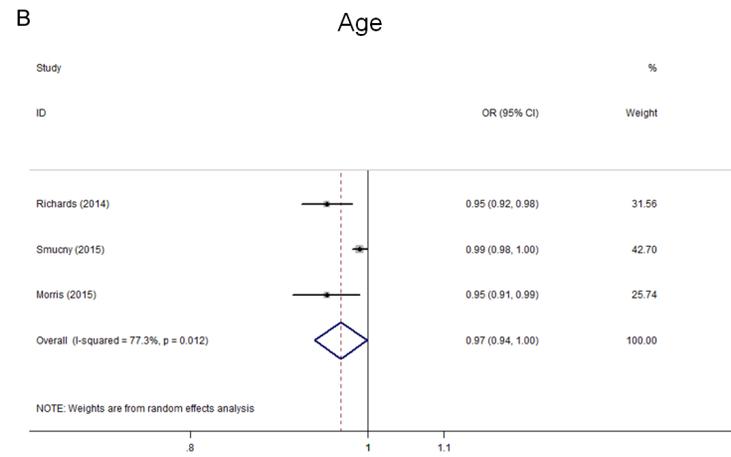
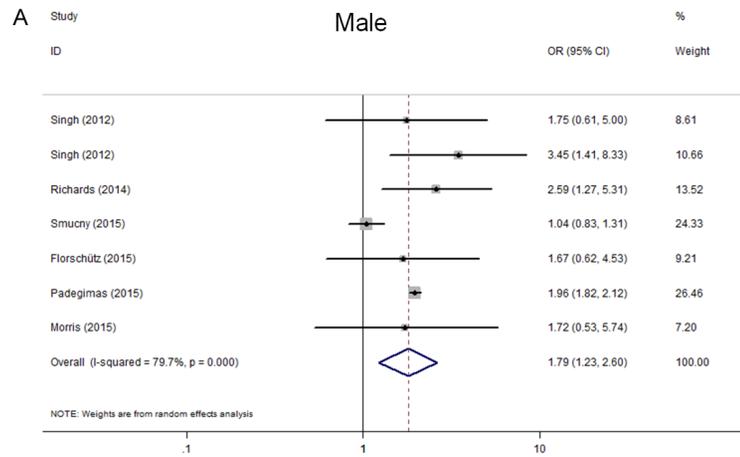
Sensitive analysis

We performed a sensitive analysis for the risk factors (male and age) presenting with significant heterogeneity by excluding outlier studies due to poorer assessment quality or a larger size of the confidence interval for some ORs. The results revealed that the I^2 -value decreased to below 50%, but the meta-analysis results for these factors did not change the significance, indicating that the results were robust. The detailed information of the sensitive analysis is presented in **Table S1**.

Discussion

Complications after primary shoulder arthroplasty are reported to range from 19% to 75%, including prosthesis loosening, periprosthetic infection, hematoma, fracture, and nerve injury [16-20]. In particular, periprosthetic infection remains a challenge, which can cause pain and disability, implant failure, and occasionally, septicemia. Diagnosis is not always easy and mostly consists of a combination of laboratory tests, clinical symptoms and radiological examinations such as routine radiography, indium scans, and microbiological swabs [21]. After primary shoulder arthroplasty, every painful shoul-

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Figure 2. A. Forest plots of the meta-analysis of male gender. B. Forest plots of the meta-analysis of age. C. Forest plots of the meta-analysis of rotator cuff arthropathy. D. Forest plots of the meta-analysis of avascular necrosis. E. Forest plots of the meta-analysis of proximal humerus fracture. F. Forest plots of the meta-analysis of nonunion of humerus fracture.

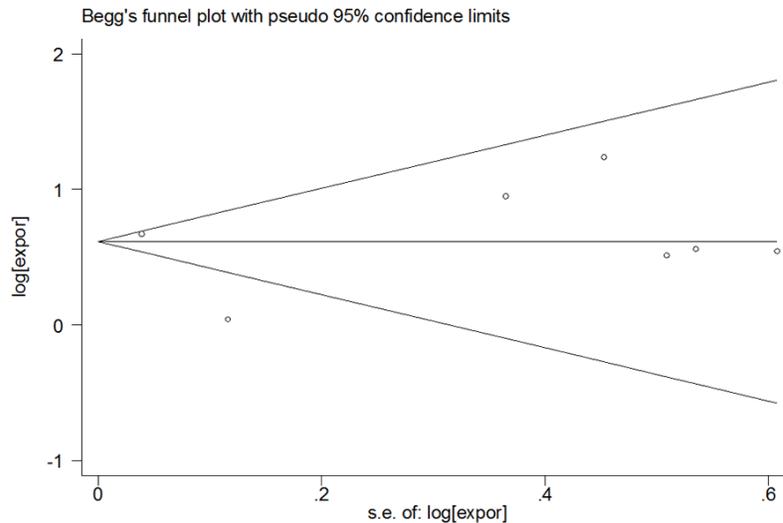


Figure 3. Begg's funnel plot for publication bias (with 95% pseudo confidence limits) of the studies that investigated sex differences between infection and non-infection after primary shoulder arthroplasty ($P=0.548$).

der should be considered potentially infected, so an immediate, detailed diagnostic examination is compulsory. Generally, the CRP level in infected implants often increases when the total WBC count is not high [22, 23]. In this meta-analysis, we investigated the very low incidence of infection after shoulder arthroplasty, and identified several risk factors associated with infection, which could be of clinical importance in screening patients at risk and in the prevention of incident infection.

Florschütz et al. [15] observed the overall infection rate after primary TSA or RTSA was 2.0%, with no significant difference between the TSA (1.7%) and RTSA (2.2%) groups. Singh et al. [5, 11] evaluated a large series of patients who underwent shoulder arthroplasty from 1976 to 2008 and found the deep periprosthetic infection rate was 1.2% after primary TSA and 1.0% after primary shoulder hemiarthroplasty. As the number of shoulder arthroplasties performed in the world continues to rise, identification of the risk factors associated with infection could gain more clinical or social-economic importance. In this systematic review and meta-analysis, the accumulated

incidence of overall infection after primary shoulder arthroplasty was 0.3%, and multiple risk factors are identified as being associated with this complication. Excluding a study which did not separate TSA from RTSA, the rate of deep infection becomes 1.1% after TSA, 2.8% after RTSA, and 1.0% in HSA cases, respectively. Some surgeons prefer to adopt HSA because it has a lower complication rate, but poor healing conditions and osteolysis of the tuberosities compromises the advantage. Likewise, there are both the advantages of avoiding osteolysis of the tuberosi-

ties and the disadvantage of the associated high complication rate in RTSA group. In the literature, the higher RTSA infection rate was thought to be associated with the larger dead space and decreased viable soft tissue coverage around the prosthesis, which facilitates bacterial colonization of the implant [24, 25].

In this meta-analysis, the significant risk factors with a high association magnitude for infection were male gender, younger age, avascular necrosis, rotator cuff arthropathy, proximal humerus fracture, and nonunion of humerus fracture. Singh et al. [11] reported males had an increased risk of infection, compared to females who underwent TSA. However, sex was not found to be a risk factor for infection in patients who underwent HSA at the same institution [5]. Although it is unclear why male patients are at higher risk than females, male patients without signs of infections have a greatly increased risk of having bacterial cultures positive for *Cutibacterium acnes* [24, 26]. Younger people are much more likely to have had rheumatoid arthritis or previous trauma, and younger males are more likely to have had serious trauma [11]. Perhaps, the poorer tissue

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in patients who suffered trauma or multi-drug therapy and the systemic effects of the patients with rheumatoid arthritis contributes a lot.

Morbid obesity was associated with a higher risk of deep periprosthetic infection after knee or hip arthroplasty [27-29]. The present meta-analysis suggests that a BMI of 30 kg/m² or greater had a non-significant trend toward an association with a greater risk of infection after primary shoulder arthroplasty. The potential reasons might be as such. On the one hand, the upper extremity, including the shoulder joint, was not load bearing, not like a knee or hip which is more affected by BMI. On the other hand, the small number of infection cases in our analysis might be also a limitation, which made it underpowered to detect such a difference in etiology of infection. Therefore, the association between BMI and infection after shoulder arthroplasty should be investigated in future studies.

Despite having the surgical indications of the shoulder arthroplasty, proximal humeral fracture (OR, 2.68; 95% CI, 1.93-3.73), avascular necrosis (OR, 2.64; 95% CI, 1.61-4.34), fracture nonunion (OR, 5.32; 95% CI, 3.52-8.02), and cuff tear arthropathy (OR, 2.14; 95% CI, 1.55-2.95) were also identified as significant risk factors for infection after primary shoulder arthroplasty in our study. Rotator cuff arthropathy describes pathoanatomical changes associated with chronic full thickness rotator cuff tears, which include erosions of the osseous structures, humeral osteopenia and restricted shoulder motion [30]. Therefore, potentially, poor preoperative conditions might be a major contributor in the higher incidence of infection. Patients with nonunion fractures may have a higher risk of infection due to previous failed internal fixation, with indolent infection or a poor soft tissue condition for wound healing [13]. Florschütz's study [15] showed that shoulders with previous operations treated by primary shoulder arthroplasty had a significantly higher infection rate (4.3%) compared to those without previous operations (1.3%), exhibiting a 3.35-fold increased risk. For patients with traumatic arthroplasty, other researchers have found a 2 to 3-times increased risk of infection compared with patients undergoing arthroplasty for osteoarthritis [5, 12]. This may be due to soft tissue trauma around

the fracture site, which could result in increased intraoperative blood loss and prolonged operation time for prosthetic height adjustment or tuberosity reconstruction, or an increased risk of hematoma formation [12, 24].

A previous review based on a small series suggested that the underlying diagnosis of rheumatoid arthritis, the presence of diabetes mellitus, the use of immunosuppressive or systemic corticosteroid medications, previous shoulder operations, or repeated intra-articular corticosteroid injections are risk factors for periprosthetic infections [31]. However, in our review we did not find any significant association between these variables and the risk of deep periprosthetic infections, in terms of rheumatoid arthritis, diabetes mellitus, ASA, and obesity (Table 2).

With infected shoulder prostheses, most of the cases reported in the literature were treated with a two-stage exchange [23]. The two-stage exchange seems to be the procedure with the best compromises between limited function and the reliable elimination of infection after surgery. The one-stage exchange ensures better functional results but allows a higher risk of persistent infection: only the findings by Ince et al. show a sufficient eradication of infection after this treatment option [32, 33].

Some limitations in this review have to be indicated. First of all, a weakness exists in this study, in that not all the ORs regarding the potential risk factors applied for the meta-analysis were adjusted because some of the studies only gave the univariate statistics rather than the multivariate. Likewise, some studies chose not to report the insignificant results or results of little or no interest, potentially leading to a considerable amount of missing data. Thus, our overall effect is more likely to overestimate or underestimate the truth. What's more, most of the included studies were retrospective and therefore had interviewer biases, which might affect the associations between risk and infection. Lastly, the measurements of risk factors differed from each other, and follow-up periods ranged widely from one year to decades. Therefore, a significant heterogeneity was unavoidable in this meta-analysis. However, after sensitive analyses, heterogeneity was resolved ($I^2 < 50\%$), showing the analyses were robust and the results reliable.

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Despite the limitations mentioned above, this study is clinically valuable to some extent. In summary, this meta-analysis suggests that male gender, younger age, avascular necrosis, rotator cuff arthropathy, proximal humerus fracture, and nonunion of humerus fracture were significant risk factors for infection after primary shoulder arthroplasty.

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Disclosure of conflict of interest

None.

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Table S1. Results of sensitive analysis for variables

Variables	OR and corresponding 95% CI (previously)	P for heterogeneity	I ²	Study excluded	OR and corresponding 95% CI (afterwards)	P for heterogeneity	I ²
Male	1.79 (1.23-2.60)	<0.001	79.7%	Smucny 2015	1.97 (1.83-2.13)	0.805	0
Age	0.97 (0.94-1)	0.012	77.3%	Smucny 2015	0.95 (0.93-0.97)	1	0