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ABSTRACT

Surgical site infection is one of the most frightening complications of surgery. Different drapes have been used as an infection prevention tool, although evidence regarding iodophor-impregnated drapes remains limited.

This meta-analysis (PROSPERO- CRD42023391651) aimed to assess if iodophor-impregnated drapes reduced the intraoperative contamination, a risk factor for infection.

We systematically searched MEDLINE, SCOPUS and Web-of-Science databases for randomized clinical trials comparing the percentage of intraoperative contamination with iodophor-impregnated drapes *versus* no-drape. Primary outcome was the percentage of contaminated swabs at the end of surgery. The meta-analysis was performed using the Mantel-Haenszel method to calculate the common effect estimate, and its random variant to account for inter-study heterogeneity.

A total of four eligible articles were identified. All were parallel group randomized controlled trials. The inter-study heterogeneity was low (I^2 = 0 %). Among the 1784 patients included in these four trials, 906

(50.8 %) received an iodophor-impregnated drape and 878 (49.2 %) received no drape. From these 1784 patients, 249 (14.0 %) had a contaminated swab at the end of the surgery: 95 (10.5 %) on the iodophor-impregnated drape group and 154 (17.5 %) on the no-drape group (RR: 0.60 [95 %CI: 0.41-0.88], $p = 0.02$).
In conclusion, iodophor-impregnated drapes are associated with lower intraoperative contamination compared to no adhesive drapes.

Keywords: Intraoperative contamination. Surgical site infection. Surgical wound infection. Surgical drapes. Adhesive plastic. Iodophor-impregnated drape. Iodine-impregnated drape.

RESUMEN

La infección de la herida quirúrgica es una complicación temida en cirugía. Se han usado diferentes adhesivos como herramienta para prevenir infecciones, aunque la evidencia respecto a los impregnados en yodo es limitada.
Este metaanálisis (PROSPERO-CRD42023391651) tiene como objetivo determinar si los adhesivos impregnados reducen la contaminación intraoperatoria, un factor de riesgo de infección.
Hemos realizado una búsqueda sistemática en Medline, Scopus y Web of Science de ensayos clínicos aleatorizados comparando el porcentaje de contaminación intraoperatoria con los adhesivos impregnados frente a no usarlos. El objetivo primario fue el porcentaje de escobillones contaminados al final de la cirugía. Se utilizó el método Mantel-Haenszel para el efecto común estimado y su versión aleatoria para la heterogeneidad interestudio.
Se identificaron cuatro artículos elegibles. La heterogeneidad interestudio fue baja ($I^2 = 0$ %). Entre los 1784 pacientes incluidos, 906 (50,8 %) recibieron adhesivo impregnado y 878 (49,2 %) no los recibieron. De estos 1784 pacientes, 249 (14,0 %) presentaron escobillón contaminado al final de la cirugía: 95 (10,5 %) en el grupo

de adhesivo impregnado y 154 (17,5 %) en el grupo de no adhesivo (RR: 0,60 [IC 95 %: 0,41-0,88], p = 0,02).
En conclusión, los adhesivos impregnados en yodo se asocian con una reducción de la contaminación intraoperatoria respecto a no utilizarlos.

Palabras clave: Contaminación intraoperatoria. Infección de herida quirúrgica. Adhesivo plástico. Adhesivos plásticos impregnados en yodo.

INTRODUCTION

Surgical site infections (SSI) are defined as infections occurring after surgery in the body part where the surgery took place (1,2). For most SSIs, the source of the invading pathogen is the patient's skin (3). Therefore, adhesive drapes (AD) are a commonly used strategy to reduce SSI, acting as a blocking barrier against the translocation of recolonizing bacteria from the adjacent skin into the surgical wound (4,5).

AD were first used in 1950 for abdominal surgery (6). They can be non-impregnated (NIAD) or iodophor-impregnated (IIAD); however, NIADs are being progressively overlooked since some studies have suggested they might associate a higher SSI incidence (7-9). Consequently, the use of IIADs has increased in the past years, although the evidence on their role in SSI prevention is limited (10,11). This scarce evidence is probably related to the fact that using SSI as a primary endpoint means large samples and extensive follow-ups. Therefore, other primary endpoints such as intraoperative contamination seem more appealing and have been increasingly used (5,12,13).

Surgical wound contamination has been established as a risk factor in the development of postoperative infection (14). Although a systematic review evaluating the effectiveness of IIAD on

intraoperative contamination was conducted in 2021 (15), it only focused only on orthopaedic surgery and was restricted to two studies, limiting the validity of the findings. The present manuscript reports a systematic review and meta-analysis of randomized clinical trials (RCT) comparing IIADs versus no drape in reducing the incidence of intraoperative contamination and included eligible articles from all surgical specialties published since the implementation of IIAD (1984).

MATERIALS AND METHODS

Study registration and ethics

This meta-analysis is reported in accordance with Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines (16). The study protocol was prospectively registered in PROSPERO (CRD42023391651) and was published elsewhere (17). Ethical approval was not required for this work.

Eligibility criteria

Included studies were English-language RCTs published between January 1984 and January 15th, 2023, conducted with adult patients (≥ 18 years of age) who underwent any kind of surgery and comparing the incidence of intraoperative contamination between those receiving IIAD versus no drape. We excluded conference abstracts, systematic reviews, case reports, non-interventional, and pre-clinical studies

Data sources and search criteria

A systematic literature search was performed based on the PRISMA guidelines (16). The search strategies are presented in Tables S1-S3. Search terms included controlled terms (Medical Subject Headings, MeSH) in PubMed, as well as free-text terms. All rendered results were imported to EndNote® version 20.4 (Clarivate, Philadelphia, PA, USA) and duplicates were removed. Titles and abstracts of identified

articles were independently screened by two reviewers (AG-S and TC) for potentially relevant studies. Those selected underwent full-text review. Discrepancies regarding inclusion were settled by a third (senior) reviewer (SV). Details of the selection process were summarized in a PRISMA 2020 flow diagram (18).

Data extraction and outcome of interest

Two authors (AG-S and TC) performed the data extraction using a Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA) template prepared prior to the literature search. Both reviewers extracted the data independently and discrepancies were settled by a third author (SV). We extracted information regarding the year of publication, patients demographics (age and sex), number of patients included, treatment characteristics, and the outcome of interest (*i.e.*, intraoperative contamination).

Quality and risk of bias assessment

Two reviewers (AG-S and TC) independently evaluated the included studies according to the Cochrane Handbook for Systematic Reviews of Interventions, version 6.3 (19). The risk of bias was assessed by the Cochrane risk-of-bias tool for RCTs (RoB2) (19). Seven domains were evaluated: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting bias, and other biases[19]. Each item was classified as low-risk, high-risk, or raising some concerns. Discrepancies were settled by a third reviewer (SV).

Statistical analysis

Statistical analyses were conducted using R® version 4.3 for Windows® [R Foundation for Statistical Computing, Vienna, Austria) with the *meta* package. The study characteristics, type of surgery, and patient demographics were reported descriptively. The

differences between the intervention and control groups were reported as mean differences (standard deviation, SD) for continuous data, and the 95 % confidence intervals (95 % CI) were calculated to measure the treatment effects. For outcome variables on different units, we used the standardized mean differences (95 % CI). Dichotomous data were synthesized as treatment risk ratio (RR) with 95 % CI to assess the treatment effect. If quantitative synthesis was not appropriate, we summarized the findings of studies and draw a conclusion. We used the Mantel-Haenszel method to calculate the common effect estimate, using its random variant in the random case to account for inter-study heterogeneity, and applied the truncated Knapp-Hartung adjustment to the standard error to provide conservative confidence limits with enhanced coverage. Heterogeneity was assessed by calculating the I^2 index.

Unit of analysis issue

For crossover studies, we used data from the first treatment period. If the trials were assessed in more than one control group, we implemented the primary analysis to combine the data from each control group. Each patient was evaluated only once during the analyses.

Missing data

We attempted to contact the corresponding author in case of missing data. If no response was obtained, we ultimately excluded the study.

RESULTS

The initial search yielded a total of 331 records. After removing duplicates (n = 19), the title and abstract of 312 unique studies were screened for inclusion. Of these, 300 papers were deemed irrelevant and 12 were retrieved for full-text assessment. Finally, eight papers did not meet the eligibility criteria and were excluded, and only four studies (10,12,13,20) were included (Fig. 1).

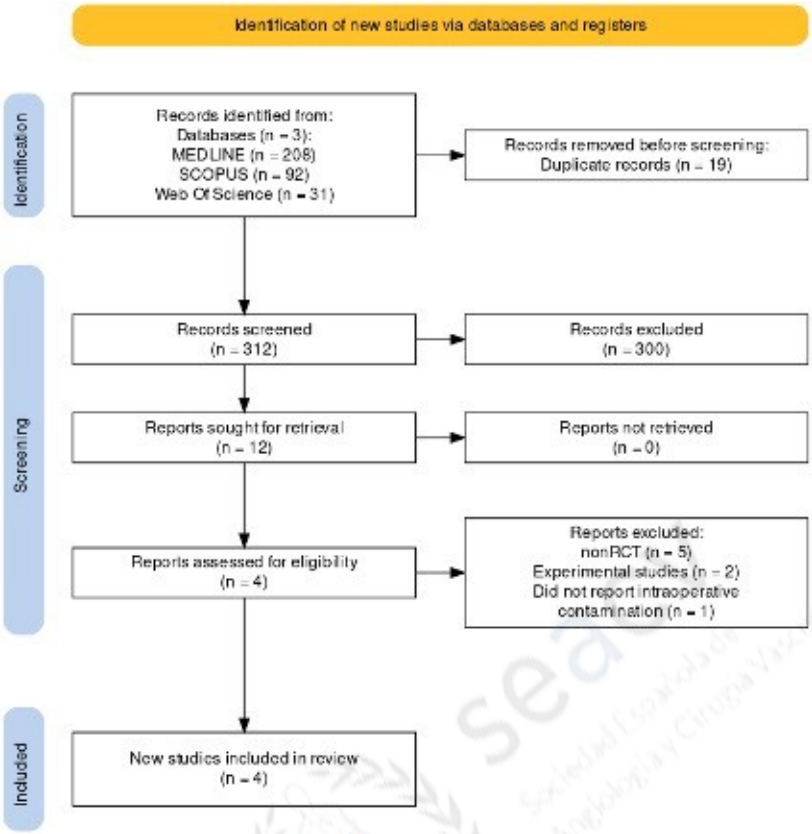

Figure 1. PRISMA flow-diagram.

Study characteristics and risk of bias assessment

All four articles were parallel-group RCTs. Two studies were conducted in America, one in Europe, and one in New Zealand, totalizing of 1,784 patients. Table I summarises the characteristics of the included RCTs. The follow-up has not been reported since the primary outcome of this meta-analysis (intraoperative contamination) was measured only at the end of the surgery. Inter-study heterogeneity was low (I^2 = 0 %).

Table I. Characteristics of the included studies

Authors	Year of publication	Country	Study type	Intervention	Comparator	No. of patients
Rezapoor et	2018	USA	RCT	IIAD	No AD	101

al. (12)						
Hesselvig et al. (13)	2020	Denmark	RCT	IIAD	No AD	1 187
Alexander et al. (20)	1985	USA	RCT	IIAD	No AD	67
Dewan et al. (10)	1987	New Zealand	RCT	IIAD	No AD	429

RCT: Randomized Clinical Trial; IIAD: Iodophor-Impregnated Adhesive Drape; AD: Adhesive Drape.

Three studies were deemed as raising some concerns regarding their risk of bias, and the remainder study was deemed as having a high-risk of bias (deviation from the intended interventions) (Fig. 2).

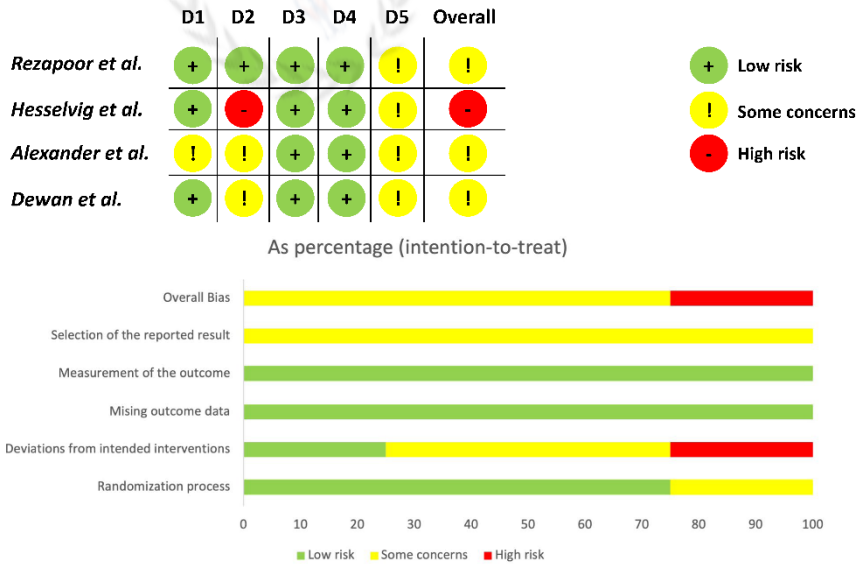

Figure 2. Risk of bias assessment. D1: randomization process; D2: deviations from intended interventions; D3: missing outcome data; D4: measurement of the outcome; D5: selection of the reported result.

Patient characteristics

Table II summarises patients' characteristics. Two studies were conducted with orthopaedic surgery patients and the remainder two with digestive surgery patients. Markedly, two studies (10,20) did not report individual baseline characteristics, although mentioning that no significant differences between their groups were detected.

Table II. Patient characteristics

Authors	**Type of surgery**	**Sex (F/M)**	**Age (years)***	**IIAD group (n)**	**AD group (n)**	**Intraop. Contamination**	
						IIAD (n)	**No AD (n)**
Rezapoor et al. (12)	Hip surgery	60/41	37.5 (17)	50	51	6	14
Hesselvig et al. (13)	Primary knee arthroplasty	714/473	68 (10)	603	584	60	90
Alexander et al. (20)	Digestive surgery	NR	NR	34	33	9	16
Dewan et al. (10)	Digestive surgery	NR	NR	219	210	20	34

F: Female; M: Male; NR: Not Reported; IIAD: Iodophor-Impregnated Adhesive Drapes; AD: Adhesive Drapes; Intraop.: Intraoperative. *Values are Mean (SD: Standard Deviation).

Outcome of interest

Out of the 1,784 patients, 906 received an IIAD (Ioban™, 3M Healthcare™, St. Paul, MN), and 878 did not receive AD. Of these 1,784 patients, 249 (14.0 %) had a contaminated swab at the end of the surgery: 95 (10.5 %) on the IIAD group and 154 (17.54 %) on the

no-drape group. This yielded a RR: 0.6 (95 % CI, 0.41-0.88), $p = 0.02$ (Fig. 3).

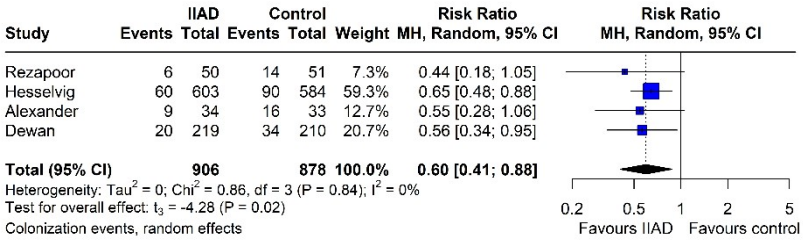

Figure 3. Forest plot comparison of intraoperative contamination incidence between IIAD and no AD. IIAD: Iodophor-Impregnated Adhesive Drape; AD: Adhesive Drape; MH: Mantel-Haenszel; CI: Confidence Interval.

DISCUSSION

The present systematic review and meta-analysis found that IIADs significantly reduced the risk of intraoperative contamination in 40.0 % when compared with no ADs (RR 0.6 [95 % CI: 0.41-0.88]).

SSI is one of the most frightening complications after surgery (21-24). ADs have been widely used as an infection prevention tool, although the evidence regarding their benefits is based in a limited number of studies (9-11,20,25,26). In fact, a 2 015 Cochrane review with a high quality of the evidence (GRADE) showed that NIAD are associated with a 23.0 % increase in SSI (RR 1.23 [95 % CI: 1.02-1.48]) (8), possibly due to a moisture increase. However, this same review could not make any strong recommendation regarding the use of IIAD and SSI. This moisture increase seen with the NIAD compared to the IIAD could be related to the fact that IIADs contain a polyester layer, which is less occlusive than the polypropylene used in NIADs (7-9). Markedly, most of the published data does not focus on SSI as primary outcome but on intraoperative contamination, provided it

does not require an extensive follow-up and has been established as a useful tool to assess the risk of SSI development (increasing even ten times the risk of infection) (14). Therefore, the rationale for conducting this systematic review was to improve the current knowledge about IIADs and intraoperative contamination.

These results are consistent with those from a 2,021 systematic review, which was restricted to orthopaedic surgery, and showed a reduction in intraoperative contamination with IIADs (OR 0.58 [95 % CI: 0.41-0.80]) (15). IIADs allegedly reduce IC because appropriate skin antisepsis does not completely remove the skin's microbiota, as some may persist in the lower skin layers. This fact could lead to microbial recolonization of the skin surface and wound edge during the surgery, which can be prevented by the using IIADs (27), due to iodophor's bactericidal properties (28). Notably, although our systematic review includes two RCTs published more than 30 years ago, both used Ioban™ (the same drape that is currently being used, the only difference being the more conformable backing in newer versions) (29).

Our study has limitations. Remarkably, this meta-analysis only focuses on intraoperative contamination, and not SSI itself, and although evidence suggests both are closely related (14), not all contaminated wounds lead to infection (15). Additionally, it is clear that the evidence regarding this topic is scarce, as only four RCTs could be included, two of them published over than 30 years ago. The overall quality of the trials was considered moderate, and three RCTs were deemed as raising some concerns and one as having high risk of bias. Finally, our search was limited to English language publications; thus, non-English language RCTs might have been overlooked.

CONCLUSIONS

The available evidence suggests that IIAD are associated with a lower intraoperative contamination compared with no AD. However, the results should be interpreted with caution, and further research is

needed to see if this improvement in intraoperative contamination is associated with a reduction in SSI.

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