

Review Article



Efficacy of Transparent vs. Pressure Dressing in Prevention of Post-Cardiac Catheterization Pain, Discomfort and Hematoma: A Systematic Review and Meta-analysis of RCTs

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Abstract

Introduction: There is lack consensus on superiority of transparent vs. pressure dressing for prevention of post-cardiac catheterization pain, discomfort and hematoma. Therefore, we conducted this systematic review and meta-analysis of available RCTs on this subject.

Methods: We performed a systematic search of RCTs published between in 2000-2019 in English language using databases including PubMed Medline, EMBASE, CINAHL, Cochrane Library, ERMED Journals, Clinical trials database, DELNET, Google Scholar and Discovery Search. Studies conducted on adult patients with femoral dressing after cardiac catheterization measuring pain, discomfort, hematoma as intended outcomes have been included. Data extraction, critical appraisal, assessment of risk bias was done and decisions on quality were made on mutual consensus. Mantel-Haenszel (MH) and odds ratio for dichotomous variables was calculated by Review Manager 5.3 software.

Results: Out of all identified studies, only 5 studies comprising 664 patients fulfilled the inclusion criteria and met the quality assessment. Incidence of discomfort (25, 333) were significantly less in transparent dressing group as compared to pressure dressing group (149, 331); odds ratio 0.10, 95% confidence interval [CI] 0.06-0.15; $I^2=0\%$, $P=0.00$. Four studies reported significantly lower number of pain cases in transparent dressing (17, 203) as compared to pressure dressing (57, 201); odds ratio 0.13, 95% confidence interval [CI] 0.03-0.59; $I^2=47\%$, $P=0.01$. However, incidence of hematoma did not reveal any significant difference between two groups.

Conclusion: Transparent dressing is a better option in patients with femoral/groin dressing after cardiac catheterization as it is more effective in prevention of pain and discomfort.

Introduction

Indian population has increased prevalence and at high risk for developing cardiovascular diseases. It was reported in 2016 that total number of people suffering from cardiovascular diseases are around 54500000 million which is an alarming data.¹ Cardiac catheterization or angiography is performed as a diagnostic measure to rule out the blocked arteries. After cardiac catheterization, the main goal is to achieve haemostasis which can be achieved by manual compression once femoral sheath has been removed and then application of either pressure dressing or transparent dressing is done.

Traditionally, pressure dressing is used to maintain direct pressure over puncture site to achieve homeostasis but studies have reported that it causes great discomfort to patient like pain, discomfort and skin trauma while removing it. Alternatively, transparent dressing is used for this purpose, which was found to have fewer patients'

discomfort as compared to pressure dressing.²⁻⁶ However, some of the studies have concluded that there were no much difference between transparent or pressure dressing in terms of hematoma.²⁻⁴ But results could not be generalized because of difference in sample population and small sample size used in studies. There are only few randomized controlled trials (RCTs) comparing efficacy of transparent vs. pressure dressing for prevention of post-cardiac catheterization pain, discomfort and hematoma. Although, individual trials are conducted but it was performed on very small sample and therefore, lack consensus in the results. Further, so far no systematic review has been done to explore the superiority of transparent dressing or pressure dressing from available randomized controlled trials. So, we conducted this systematic review and meta-analysis of available RCTs to create strong evidence of best practice for patients that could also bring a change in conventional practices

of dressing after cardiac-catheterization. We aimed to explore the effectiveness and safety of transparent dressing vs. pressure dressing for prevention of post-cardiac catheterization pain, discomfort and hematoma.

Materials and Methods

We retained systematic review methods developed by Cochrane Handbook for Systematic Reviews of Interventions.⁷ Studies were reported as per PRISMA (Preferred Reporting Items of Systematic reviews and Meta-Analyses) guidelines.⁸ Only randomized controlled trials were included in this systematic review with interest of comparing transparent dressing and pressure dressing among patients with cardiac catheterization to assess the incidence of pain, hematoma and discomfort as a primary outcome.

We performed a systematic search in nine different databases including PubMed, Medline, EMBASE, CINAHL, Cochrane Library, ERMED Journals, Clinical trials database, DELNET, Google Scholar and Discovery Search. The review explored studies published between 2000-2019 in English language with all identified index terms and keywords. For search in different databases following keywords and MESH terms were used in combinations. “Coronary Angiography/adverse effects”, “Coronary Angiography/therapeutic use”, “Coronary Angiography/nursing”, “Coronary Angiography/standards”, “Bandages”, “Haemorrhage”, “prevention and control”, “Compression Bandages” “pressure dressing”, and “transparent dressing”. The search was also extended to peer reviewed journals

and references of similar studies were also reviewed thoroughly to gather maximum number of eligible studies for this meta-analysis (Appendix 1). Figure 1 show PRISMA flow chart.

Two reviewers (SKM & KT) independently searched and did screening of the records for title and abstracts. Later, full text articles were extracted and assessed to identify eligibility for inclusion by two reviewers (SKM & KT) independently. Two reviewers (SKS & BK) cross-checked all the data and solve any discrepancy between two reviewers if present. For incomplete findings or missing data in selected research articles, corresponding authors were contacted through emails and queries were asked regarding allocation concealment, blinding of participants and outcome measures. Corresponding authors of four studies³⁻⁶ addressed our queries in detail but we could not receive any information from corresponding author of one study² and interpretation of the findings were done as per reviewers’ mutual understanding.

Cochrane Collaboration Risk of Bias Tool for Randomized Controlled Trials⁷ was used for assessment of risk bias in the study by two primary reviewers (SKM & KT). Risk of bias in studies was reviewed under different domain like random sequence generation, allocation concealment, selective reporting, participants and personnel blinding, outcome assessment blinding, incomplete outcome data and for other bias (Figure 2). All these domains were assessed for low risk, high risk and unclear risk and it will be marked of good quality if all the domains studied are at low risk of bias, fair quality in case

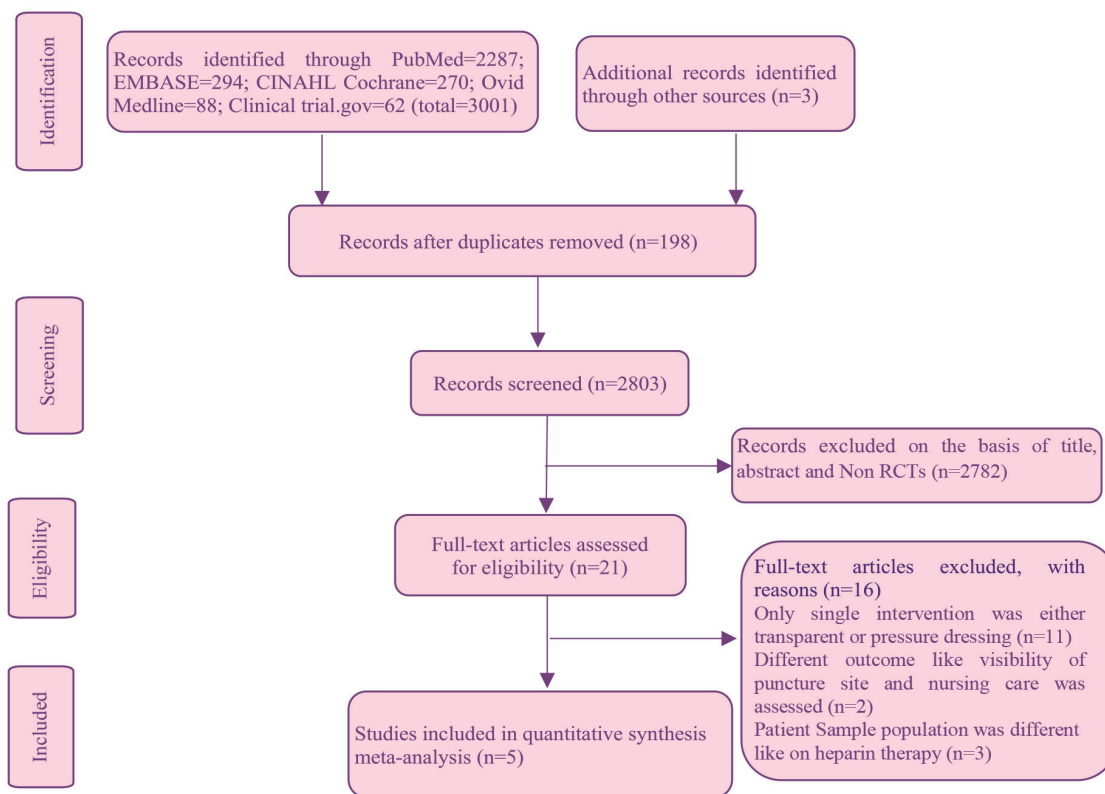


Figure 1. PRISMA flow chart

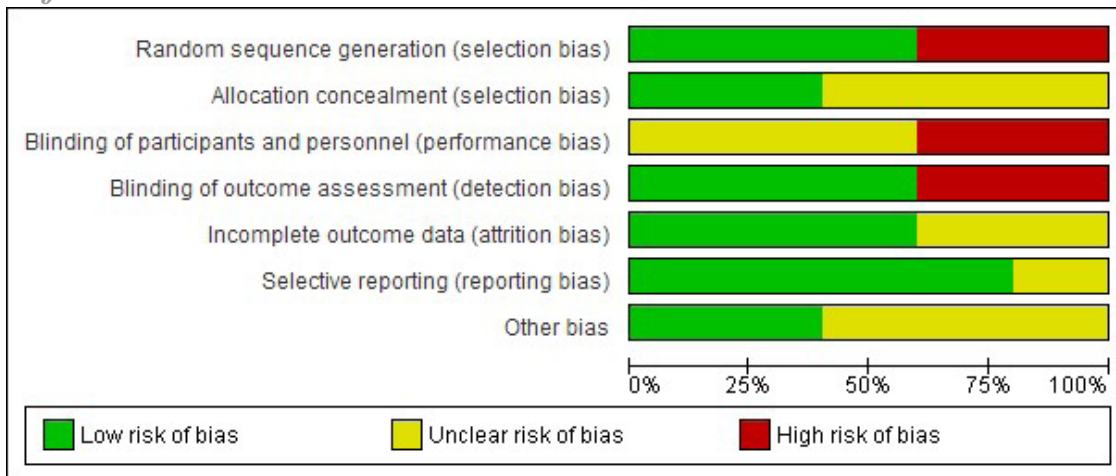


Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

one domain is at high risk and two are unclear for risk and poor quality if two or more domains are at high risk or unclear risk of biasness. Third & Fourth reviewer (SKS & BK) were involved to solve discrepancies between primary reviewers while assessing studies for risk of biasness.

Comprehensive meta-analysis was performed using the RevMan 5.3 software. Mantel-Haenszel (MH) and odds ratio⁹ for dichotomous outcome variables, including incidence of pain, hematoma and discomfort. We had planned to use I^2 statistics to rule out the inconsistencies between studies and its overall impact on meta-analysis. The P -value < 0.05 was considered as statistically significant. 'Fixed effect modelling' and 'Random effect modelling' were used to find out the heterogeneity. Studies with I^2 less than 40% was considered as small level of heterogeneity and therefore have minimum impact on meta-analysis. We have presented data in funnel plot which reveals about size of the study and explains about publication bias.

Results

We combined different search methods as mentioned in study selection and a total of 3001 studies were extracted from different databases and 3 from other sources. A total of 2287 articles was identified from PubMed & Discovery, 294 from EMBASE, 270 articles combined from CINAHL Cochrane Library, 88 from Ovid Medline and 62 articles from Clinical Trials Database. Finally, 5 articles²⁻⁶ including 664 patients who met inclusion criteria and quality standards were included for meta-analysis (Figure 1).

Randomized controlled trials which were included in this meta-analysis were from India,⁴ Singapore,³ West Virginia,⁵ Thailand,⁶ Saudi Arabia.² Out of all, two studies^{2,5} had sample size less than 100 and three studies^{3,4,6} had included more than 100 participants for their study. In one trial,⁵ participants were divided in two groups i.e. with heparin therapy or without heparin therapy but there was no difference in reporting of outcomes so, group without heparin therapy was included for this meta-analysis.

One other trial conducted in Singapore³ had reports of additional outcomes like ability to observe the groin site, but as it did not impact outcome used for this review, so we have excluded findings related to this outcome. Other three trials^{2,4,6} had reported of outcomes, i.e. pain, hematoma and discomfort in a similar way. All of the studies were conducted in super speciality hospitals and settings of the study were CCU. Data from studies revealed that nurses were involved in assessment of outcomes may be because of their trained skills in patients' assessment. Details of included studies for type of interventions and outcome measures are described in Table 1.

The methodological quality of all the included studies are described in figure 2 & 3.

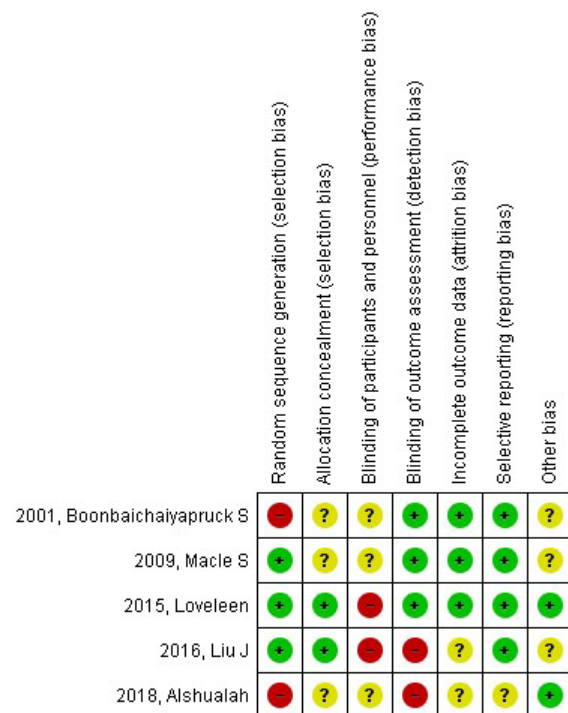


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

Table 1. Characteristics of included studies

Year, Author (Setting)	Study design	Number of participants in total and each group	Participants' characteristics Mean age (SD) Gender (%)	Intervention ^a	Pain TD,PD ^b	Results Hematoma TD,PD ^b	Discomfort TD,PD ^b
2001, oonbaichaiyapruck S et al., ⁶ (Thailand)	Open randomized controlled trial	Total: N=126 TD: n=63 PD: n=63	59.22 (9.18) Male (49) Female (51)	Manual compression at puncture site= 20-30 minutes Pressure Dressing: Elastic adhesive bandage (Tensoplast) 7.5cm in width Transparent Dressing: 3M tegaderm light dressing with an absorbent pad of 5cm x 7cm)	17,31	1,3	7,35
2009, Macle S et al., ⁵ (West Virginia)	Single blinded randomized controlled trials	Total: N=68 TD: n=35 PD: n=33	62(13.3) Male (68) Female (32)	Manual compression at puncture site= 30 minutes Pressure dressing: 10cm elastikon elastic tape (Johnson & Johnson, New Brunswick, New Jersey) Transparent dressing: Opsite IV 3000 Standard 10x14cm transparent dressing (Smith & Nephew, London, England) over one 5x5cm gauze sponge	0,4	0,2	1, 3
2015, Loveleen et al., ⁴ (India)	Double blinded randomized controlled trials	Total: N=130 TD: n=65 PD: n=65	57(11.4) Male (82) Female (18)	Manual compression at puncture site= 15-25 minutes Pressure dressing: Manually prepared dressing with gauze and dynaplast elastic bandage Transparent dressing: 10x12cm tegaderm thin film dressing (Smith & Nephew, Punjab, India)	0,4	0,0	10,42
2016, Liu J et al., ³ (Singapore)	Open randomized controlled trial	Total: N=260 TD: n=130 PD: n=130	63(14.2) Male (66) Female (34)	Manual compression at puncture site= 20 minutes Pressure dressing: 10cm x4.5m elastoplast Transparent dressing: 10 x 12 cm tegaderm Film over gauze sponge folded into four on puncture site	0,0	5,5	7,51
2018, Alshualah ² (Saudi Arabia)	Single blinded randomized controlled trial	Total: N=80 TD: n=40 PD: n=40	55(10.7) Male (30) Female (70)	Manual compression at puncture site= 20-30 minutes Pressure dressing: Manually prepared gauze dressing covered with 2 bulky abdominal gauze pads and tape. Transparent dressing: Tegaderm film applied over 2x2 inch (5x5 cm) gauze sponge	0,18	0,0	0,18

^aAll participants underwent diagnostic catheterization and angiography and right femoral approach with sheaths size ranging between 5-8 F were used, ^bTD: Transparent Dressing and PD: Pressure Dressing

Two studies^{2,3} reported biasness in blinding of assessment as same nurses involved in care was used for assessment and data collection. Two studies^{2,3} reported incomplete data, i.e., one study³ did not give data on patients' pain after removal of dressing while other study² failed to report data of hematoma assessment. In addition to all these, only two studies^{3,5} explained method and procedure used for calculation of sample size while other three^{2,4,6} did not give any justification for the sample size they have used for the study. It can be said that included studies had risk of biasness for some of the components, but the chances of imprecision are minimum as we have more than 400 participants i.e., 664 participants in total for this meta-analysis. However, it was also observed that there was uniformity in all comparison made by all primary studies for the desired outcome. Hence, the result of this can be considered appropriate to draw appropriate

conclusions for study outcomes.

The incidence of pain was reported in four trials and there were total (17,203) in transparent dressing group and (57,201) in pressure dressing group. For a pooled proportion of result, Mantel-Haenszel and odds ratio was used and it was reported that MH OR was 0.13 (95% CI: 0.03 to 0.59) [$P=0.00$, $I^2=44\%$]. With this finding we can clearly state that there were around 87% less chances of pain incidence among participants with transparent dressing as compared to pressure dressing (Figure 4).

Hematoma at puncture site was reported by total five trials which included a total of 324 and 307 patients in transparent dressing group and pressure dressing group respectively. Two studies reported that there was no single incidence of hematoma from participants of both groups. The overall incidence of hematoma was (6,324) in transparent dressing and (8,307) in pressure dressing

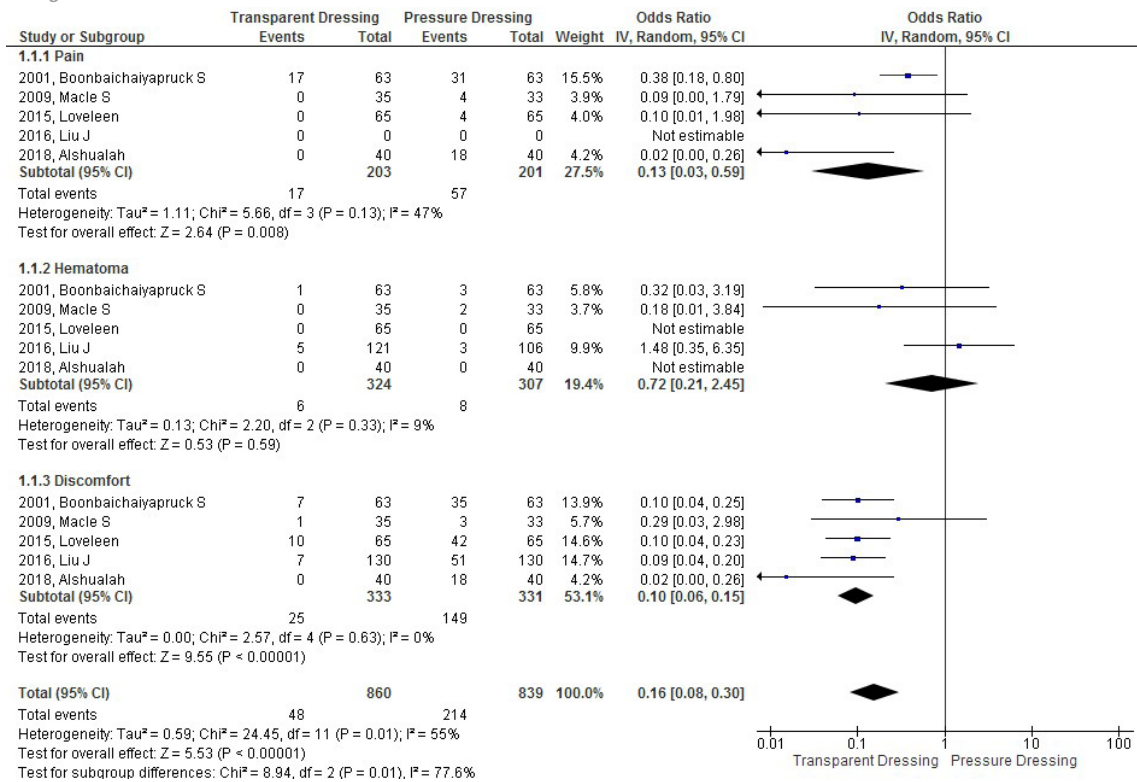


Figure 4. Forest plot of comparison transparent dressing VS pressure dressing, outcome: pain, hematoma, and discomfort

group. Hence, the MH OR for incidence of hematoma among patients with transparent dressing was 0.72 (95% CI between 0.21-2.45) [$P=0.59$, $I^2=9\%$]. P -value >0.05 states that there was no significant difference in hematoma incidence among patients of transparent dressing and pressure dressing (Figure 4).

Transparent dressing was found to be effective than pressure dressing in term of discomfort. There was less incidence of discomfort reported by patients for whom transparent dressing was applied, i.e., (25,333) and (149,331) patients reported discomfort when pressure dressing was applied. The MH OR for discomfort among patients with transparent dressing as compared to pressure dressing was 0.10 (95% CI between 0.06-0.15) [$P=0.00$, $I^2=0\%$]. Hence, there was a 90% reduction in the incidence of discomfort when transparent dressing is applied in comparison to pressure dressing (Figure 4).

Publication bias in included trials was studied with funnel plot for the outcome variables like pain, hematoma and discomfort. Outcomes of studies shown a skewed pattern which indicates the risk of publication bias. Although, this observation is suggestive and rank test can be used further to establish the correlation between effect size and its corresponding variance. We did not use rank test because we had less than ten studies for this meta-analysis (Figure 5).

Discussion

Post-cardiac catheterization dressing plays crucial role in preventing complications like hematoma, arterial occlusion, and discomfort.⁴ Few corporate hospitals

in our country use transparent dressings after cardiac catheterization but still there are some rigid beliefs of physicians and nursing personnel regarding the use of pressure dressing and they favour pressure dressing especially to prevent the incidences of hematoma. Findings of this systematic review and meta-analysis show that transparent dressing is superior to pressure dressing in terms of pain and discomfort while for hematoma it shows no significant difference between both types of dressings.

Randomized trials done earlier to compare effectiveness of transparent or pressure dressing has shown that tight dressing with sticky material is not at all required as it did not bring any significant difference in patients' discomfort

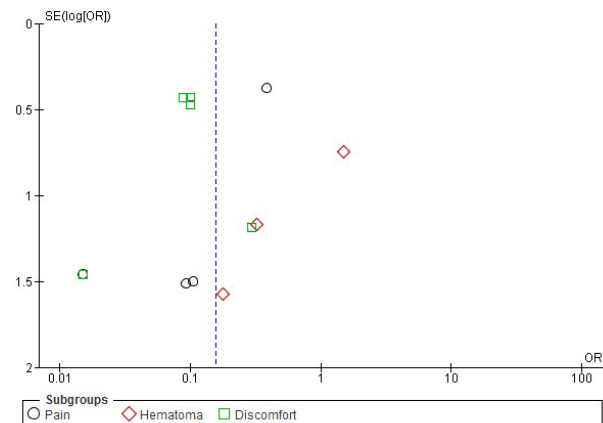


Figure 5. Funnel plot of comparison transparent dressing vs pressure dressing, outcome: combined data for pain, hematoma and discomfort

and pain.²⁻⁶ Although, few studies^{5,6} observed interesting findings that patients with pressure dressing had reported more incidence of hematoma than transparent film dressing. Most of the patients reported that pressure dressings were more uncomfortable and hair pulling effect while dressing removal can be one of the factors for this. On the other hand, dressing with Tegaderm was considered to be more comfortable because of its ease of application and removal.⁶

There were few other trials which were carried out recently and they reported some contradictory findings. Studies carried out by Loveleen et al.,⁴ and Alshualah² found that there was no case of hematoma in both the groups i.e. transparent dressing and pressure dressing. Moreover, studies²⁻⁶ reported that incidences of pain and discomfort were fewer in transparent dressing as compared to pressure dressing group. The findings of this systematic review and meta-analysis clearly states that there was a reduction in pain by 86% and discomfort by 90% among patients with transparent dressing as compared to pressure dressing.

However, for pain and discomfort studies found that transparent film dressing is more suitable but for the incidence of hematoma there were contradictory findings. One trial conducted by Liu J et al.,³ reported that patient with transparent dressing had more incidences of hematoma as compared to those who had applied pressure dressing. The present meta-analysis found that the overall incidence of hematoma was (6, 324) in transparent dressing and (8, 307) in pressure dressing group states that there was no significant difference in hematoma incidence among patients of transparent dressing and pressure dressing. As per earlier studies, the tension created between anterior iliac spine and patient's thigh because of pressure dressing can be a cause of more reported incidence of hematoma as compared to transparent dressing where there is no such tension or friction occur.^{4-6,10} Studies where there were no reported cases of hematoma in both the groups found that manual compression applied before application of dressing if given appropriately can prevent the incidence of hematoma.^{2,4} It was also observed that the use of smaller catheter size i.e. 5F can also reduce the risk of hematoma.^{4,6}

It has been noted from study findings that dressing with transparent film causes some other benefits which also facilitate nursing assessment and patient comfort.^{3,6,11} Nurses reported that while transparent dressing was in place it was easier for them to do puncture site assessments while in case of pressure dressing clear visualization of site was not possible. Another important benefit was minimum skin reactions and lesser discomfort because the border of transparent film dressing contains hypo allergens.^{6,11} Patients with light tegaderm dressings also reported subjective feelings of much comfort in some studies.^{3,5,6,12} This type of dressings are commonly waterproof and hence, it allows patients to take a bath and perform basic hygiene that also minimized the chance of infection at puncture site.^{10,11} Patients' comfort is of prime

importance and changes in conventional practices are required at all level starting from placement of dressing till complete recovery and studies have also reported that patients' pain, hematoma and discomfort do not depend only on the type of dressings but also due to the size of sheath used in cardiac catheterization.^{13,14}

The result of this meta-analysis suggests that transparent dressing should be used rather than conventional pressure dressing as it brings more comfort to patients and less painful. It is important that finding of this analysis will be taken into consideration to formulate the change in policy and create awareness among physicians and nurses to follow evidence based practice. Turning practice towards transparent dressing will not only be beneficial for patients, but at the same time it would be equally important for nurses as it enhances visibility of puncture site and nurses' skills to manage patients. Meta-regression of included studies was not performed as we have less number of trials available.¹⁵ Moreover, data regarding visibility of assessment site were not analysed as it was only reported in two studies. Although we have performed detailed literature search in various databases, but still publication bias is present.

Conclusion

Use of transparent dressing for puncture site dressing after cardiac catheterization is a better choice than pressure dressing as it results in lower incidence of pain, hematoma and discomfort. We predicate recommendations for physicians, nurses and policy makers to encourage the use of transparent dressing in clinical settings to promote positive outcomes. Further studies can be performed to explore the effectiveness of a transparent dressing on assessment of puncture site and other complications with large sample size.

Acknowledgments

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Ethical Issues

This project was a systematic review and meta-analysis so, do not require ethical approval as there was no direct information or intervention performed on human sample. Institutional ethical committee has refrained authors from ethical permission.

Conflict of Interest

Authors have no conflict of interest in carrying out this systematic review.

Author's Contributions

SKS: Developed concept of this systematic review. Thoroughly involved in data acquisition and solved discrepancy in the risk of bias assessment. Involved in data analysis, manuscript preparation, editing and review; KT: Independently searched literature and did screening of the records for title and abstracts.

Research Highlights

What is the current knowledge?

There are only few randomized controlled trials (RCTs) comparing effectiveness of transparent dressing vs. pressure dressing. Although, studies have concluded that there were no much difference between transparent or pressure dressing in terms of hematoma but results lack consensus and could not be generalized.

What is new here?

This systematic review and meta-analysis of available RCTs generated a strong evidence that transparent dressing is a better option in patients with femoral/groin dressing after cardiac catheterization.

Later, full text articles were extracted and assessed to identify eligibility for inclusion. Performed risk of bias assessment for all the included studies. Performed statistical analysis and also involved in manuscript preparation and editing; SKM: Performed extensive literature search and also did independent risk of bias assessment for all the included studies. Involved in statistical analysis, manuscript preparation and editing; BK: Involved in assessing eligibility of included studies and solved discrepancy in the risk of bias assessment. Performed data analysis and also helped in manuscript preparation.

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Appendix 1. Search strategy

Pubmed Central: (Total =2287 using Mesh Term)

("Coronary Angiography/adverse effects"[Mesh] OR "Coronary Angiography/nursing"[Mesh] OR "Coronary Angiography/standards"[Mesh] OR "Coronary Angiography/therapeutic use"[Mesh])

("Bandages"[Mesh]) AND "Coronary Angiography"[Mesh]

((("Coronary Angiography"[Mesh]) AND "Bandages"[Mesh]) AND "Hemorrhage"[Mesh])

((("Coronary Angiography"[Mesh]) AND "Bandages"[Mesh]) AND "prevention and control" [Subheading])

((("Coronary Angiography"[Mesh]) AND "Bandages"[Mesh]) AND "Hemorrhage"[Mesh]) AND "prevention and control" [Subheading])

("Coronary Angiography"[Mesh]) AND "Compression Bandages"[Mesh]

((("Coronary Angiography"[Mesh]) AND "Compression Bandages"[Mesh]) AND "Hemorrhage"[Mesh])

((("Coronary Angiography"[Mesh]) AND "Compression Bandages"[Mesh]) AND "prevention and control" [Subheading])

((("Coronary Angiography"[Mesh]) AND "Compression Bandages"[Mesh]) AND "Hemorrhage"[Mesh]) AND "prevention and control" [Subheading])

EMBASE & Medline Search (Total=382 using Emtree thesaurus)

coronary AND angiography AND transparent AND dressing AND 'pressure dressing' AND [randomized controlled trial]/lim AND ([adolescent]/lim OR [young adult]/lim OR [adult]/lim OR [middle aged]/lim OR [aged]/lim OR [very elderly]/lim) AND [2000-2019]/py
(('coronary angiography'/exp OR 'coronary angiography' OR (coronary AND ('angiography'/exp OR angiography)))) AND ('compression bandages'/exp OR 'compression bandages' OR (('compression'/exp OR compression) AND ('bandages'/exp OR bandages)))/py
(('coronary angiography' OR (coronary AND angiography)) AND ('pressure dressing'/exp OR 'pressure dressing' OR (('pressure'/exp OR pressure) AND ('dressing'/exp OR dressing))) OR 'transparent dressing'/exp OR 'transparent dressing' OR (transparent AND ('dressing'/exp OR dressing))) AND [2000-2019]/py
(('coronary angiography' OR (coronary AND angiography)) AND ('pressure dressing'/exp OR 'pressure dressing' OR (('pressure'/exp OR pressure) AND ('dressing'/exp OR dressing))) OR 'transparent dressing'/exp OR 'transparent dressing' OR (transparent AND ('dressing'/exp OR dressing))) AND [randomized controlled trial]/lim AND [2000-2019]/py