

Medicated adhesive dressing is a safe and non-inferior cutaneous seal as compared to compound tincture benzoin dermal seal for percutaneous interventions

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ABSTRACT

Background: Compound tincture benzoin (CTB) is used as a post-procedure skin seal antiseptic agent since ancient times; but this drug is reported to cause allergic contact dermatitis and other unwanted side effects. Our aim of the present study was to compare alternative agent like Medicated Adhesive dressing (MAD) with CTB as a post-procedure skin seal dressing. **Design:** This prospective randomized controlled experimental study included an equal number of patients in MAD and CTB as a post-operative seal dressing material for percutaneous interventions. Both the groups were graded for various efficacy parameters like comfort, applicability, dressing material, and immediate post-operative complications by operating doctor and attending nurse with a maximum 10 points in each group. **Results:** 120 patients were studied in each MAD and CTB group. Out of total patients 31.25% were males and the mean age of the patient was 33.56 ± 11.10 . Allergic contact dermatitis developed in 9 (7.49%) of CTB group and in 1 (0.83%) of MAD group ($P < 0.002$), while local site skin infections were noted in 8 (6.67%) of CTB group and in 1 (0.83%) of MAD ($P < 0.002$). Operating doctor graded MAD and CTB to 7.60 ± 0.49 and 3.62 ± 0.48 ($P < 0.003$); and attending nurse 7.40 ± 0.49 and 3.41 ± 0.49 ($P < 0.003$) respectively. **Conclusion:** MAD is a safe, efficient and non-inferior alternative dressing material for post-procedure skin incision seal in comparison to CTB.

Keywords: Compound tincture benzoin, cutaneous seal dressing, medicated adhesive dressing, non-inferior dressing material, percutaneous interventions, skin incision

Background

The present time is an era of minimally invasive surgery and due to advances in the field of interventional radiology, numbers of percutaneous diagnostic, and therapeutic procedures have been

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increased substantially.^[1] In any percutaneous procedure, the skin incision is exposed to the atmosphere, so post-procedure skin incision wound care is utmost important.^[2] Tincture benzoin is an age-old pharmacy ingredient; and because of its antiseptic and adhesive property, it is commonly used for percutaneous procedure skin incision dressing.^[3,4] Compound tincture benzoin (CTB) is a mixture of benzoin, aloe, storax, and tolu balsam in alcohol base.^[5] CTB dressing seal is neither

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air proof nor waterproof and it can stain clothes as well. It sticks to hand gloves rubber during seal dressing of skin incision, so it is difficult to apply CTB dressing with gloves. Many cases of mild to severe contact dermatitis have been reported with the uses of CTB in various studies.^[6-14] It is available in 100 ml or more volume multi dosed sterile bottles and its requirement is about 10 ml in each procedure. As per the recommendations, after opening the sterile bottle of tincture benzoin, it should be used immediately and the unused liquid can't be used for the next procedure, because the growth of the virulent organisms in opened CTB bottle has been reported.^[15]

Multi-channel internal jugular venous (IJV) catheters are routinely used for various indications in the intensive care unit and if the catheter is kept for a long time cutaneous-venous fistula may develop at the puncture site. If airtight adhesive material is not applied properly after IJV catheter removal, significant venous air embolism with catastrophic hemodynamic instability have been reported in some cases.^[16,17] Looking to above demerits of CTB, alternate post-procedure skin seal agent was thought of.

Medicated adhesive dressings (MAD) are an easily available and cost-effective alternative CTB dressing. It is made up of woven fabric or latex strip with antiseptic central dressing pad (neomycin or equivalent) and remaining part of the strip have adhesive property for skin adherence and is available in sterile ready to use single pack.^[18-20] As per the authors' knowledge; ours is the first study, comparing CTB with a medicated adhesive dressing. Our aim of the present study was to compare MAD with conventional CTB as a skin sealing dressing material after percutaneous interventions.

Materials and Methods

This randomized, prospective, experimental study was conducted to compare CTB and MAD as a post-procedure dressing skin seal at a multispecialty hospital of Ahmedabad city of India from March 2016 to January 2018. The study protocol was approved by the local hospital committee. Consent of the patient regarding the random selection of either MAD or CTB as a post-procedure dressing as well as participation in the research study was taken [Annexure 1].

Patients having age above 18 years undergoing percutaneous diagnostic or therapeutic interventions who agreed to participate in the study were included. Procedures which required primary suturing or indwelling catheter *in situ* and terminally ill patients were excluded from the study. Authors first approached a doctor and a nurse who were regularly performing and assisting percutaneous procedures; and were assigned to participate in the study. After explaining detail study protocol, they were requested to judge and grade both MAD and CTB as a post-procedure skin incision dressing as per pre-printed feedback form of five efficiency parameters like comfort level of operator and assisting nurse, the complexity of the application, hygienic impression, post procedure cloth staining and hemostatic and sealing quality.

The operator and attending nurse have graded pre-decided parameter of the dressing materials, 0 point for most inferior and 2 points for very superior at the end of the study. Each of the parameters was carrying 2 points with a total of a maximum of 10 points in each feedback form [Annexure 2].

Selection of dressing materials MAD or CTB to be used as a skin dressing for post-procedure cutaneous incision was done randomly. Band-Aid strips were used as a MAD dressing and sterile cotton soaked in CTB from the multi-dose bottle was used as a CTB dressing. All the procedures were performed by the same operator and were assisted by the same nurse every time. Patients were observed for 24 hours for procedure related complications and indoor treatment as per individual case was continued. Data analysis was done with Epi-info software. Both the groups were compared using student – *t* test for continuous and chi-square tests for categorical variables. *P*-value < 0.05 was considered significant.

Results

A total of 244 patients were included in the study and out of them 4 were excluded, 2 were having abnormal coagulation profile, one was severely ill and one patient due to sudden unexplained shock before the procedure. Totally, 240 pair of filled feedback forms were received from operating doctor and assistant nurse for evaluation after study of 240 subjects having different procedures. MAD and CTB were used as a post-procedure sealing dressing in 120 patients in each group. The mean age of the patients was 33.56 ± 11.10 , males were 75 (31.25%) and 165 (68.75%) were females. Diabetes mellitus was detected 13 (10.83%) in MAD and 11 (9.16%) in CTB, while hypertension 12 (10.00%) in MAD and 9 (7.5%) in CTB group, respectively [Table 1].

Numbers of percutaneous procedures performed were abdominocentesis 47 (19.58%), thoracocentesis 52 (21.67%), liver abscess drainage 47 (19.58%), lumbar puncture 46 (19.16%), and tru-cut tissue biopsies 48 (20.00%). Allergic contact dermatitis occurred in 9 (7.49%) of the CTB group and in 1 (0.83%) of the MAD group. In CTB group out of total 9 allergic contact dermatitis, eight cases were of local dermatitis and in one case it was a severe generalized form of allergic dermatitis. Procedure site local skin infections were noted in 8 (6.67%) of the CTB group and in 1 (0.83%) of the MAD group. Operating doctor and attending nurse graded MAD to 7.60 ± 0.49 and 7.40 ± 0.49 ; and CTB to 3.62 ± 0.48 and 3.41 ± 0.49 respectively [Table 2].

Discussion

Extensive and intense research of wound care management and innovative dressing materials are current research projects at many institutes.^[21] Skin injury due to dressing material adverse reactions are recently recognized dermatological disorders and researchers are working to find out means for prevention and treatment of these iatrogenic disorders.^[2] Third generation wound dressing materials have revolutionized local skin wound dressings and prevented many complications related to conventional skin dressings.^[22,23]

CTB is used as a post-procedure seal dressing since ancient time.^[3,4] Clinical research trials and literature comparing CTB with other alternates are not found in spite of extensive search. Many studies have demonstrated allergic contact dermatitis with the use of tincture benzoin.^[6-14] Scardamaglia L *et al.* have reported 45 (9.43%) patients suffered allergic contact dermatitis due to tincture benzoin of total 477 patients at a dermatology clinic in 1999 and out of 45 allergic reactions, 14 (2.93%) were severe generalized reactions.^[6] William D *et al.* reported 19 (9.50%) cases of contact dermatitis out of 200 patients after doing patch testing with tincture benzoin.^[8] In our study, 7.49% patients suffered allergic contact dermatitis in CTB group and 0.83% patients had a severe generalized reaction; while in MAD group only 0.83% had an allergic reaction and none of them had the severe reaction.

Our study result showed that allergic contact dermatitis (7.49% vs. 0.83%) and local procedure site skin infections (6.67% vs. 0.83%) were more common in CTB group in compare to MAD group with a *P* value of less than 0.02. Average grades for sealing material by the operator for MAD and CTB were 7.60 ± 0.49 and 3.62 ± 0.48, and by assisting nurse 7.60 ± 0.49 and 3.41 ± 0.49 with a *P* value < 0.003. These four parameters had statistically significant *P* value for MAD as a superior seal dressing as compare to CTB. Diabetes mellitus and hypertension were more common in MAD group in compare to CTB. There was no procedure-related or systemic disease related difference of odds ratio even after the adjustment. Kerrigan *et al.* after studying adhesive dressing strip (3 M Steristrip S) for primary incision closure in comparison to conventional suturing concluded adhesive dressing strip as a better wound closure alternative and it was patient as well as operating doctor friendly material.^[24] Lounnis D *et al.* also reported adhesive strip as a superior closure material, for small length incision wounds.^[25] Findings of our study match with the findings of Kerrigan *et al.* and Lounnis D

et al. as both the studies showed MAD as a better incision wound closure material.

Our study has certain limitations. In our study sample size was small and dressing material in each group was graded from 1 to 10 efficiency score by operating doctor and attending nurse; this grading may have subjective human errors. It is reported that CTB has cross allergic dermatitis reactions with other agents also.^[8,9] We have not done a pre-procedure screening of contact dermatitis for either CTB or MAD and the previous allergy to either of the two agents may alter the study results.

Conclusion

The sterile medicated adhesive dressing is a safe, efficient and non-inferior alternate dressing material for post-procedure skin incision seal in compare to conventional compound tincture benzoin. However, the study results should be confirmed by further large size comparative randomized controlled trials.

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Conflicts of interest

There are no conflicts of interest.

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Table 1: Demographic features

Character	MAD n=120	CTB n=120
Age (Mean)	33.73±11.16	33.39±11.09
Male	37 (30.83%)	38 (31.67%)
Female	83 (69.17%)	82 (68.33%)
H/O diabetes mellitus	13 (10.83%)	11 (9.16%)
H/o Hypertension	12 (10.00%)	9 (7.50%)

Table 2: Comparison between MAD and CTB

Character	MAD n=120	CTB n=120	P
Average operating Doctor Grading	7.60±0.49	3.62±0.48	<0.03
Average Nurse Grading	7.40±0.49	3.41±0.49	<0.03
Allergic Skin Reaction	1 (0.83%)	9 (7.49%)	<0.02
Local Site Skin Infection	1 (0.83%)	8 (6.67%)	<0.02
Abdominocentesis	24 (51.06%)	23 (48.93%)	0.74
Thoracocentesis	27 (51.92%)	25 (53.19%)	0.75
Liver abscess drainage	22 (46.80%)	23 (53.19%)	0.74
Lumbar puncture	22 (47.82%)	24 (52.17%)	0.76
Trucut biopsy	23 (47.91%)	25 (52.08%)	0.74

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Annexure 1: Consent form

I patient name Mr/Mrs _____ AgeYear is agreeing and consent for procedure.....to be performed under local anaesthesia by Dr.....

Doctors and hospital staff has explained to me regarding the procedure and its possible complications in detail in language understandable to me. I also agree to participate in the research study of post procedure dressing seal either tincture benzoin or Medicated adhesive dressing (Band- Aid). These sealing agents will be selected on random base and blindly. These research data will be published in medical journal and my personal identity will not be disclosed in any publication without my written permission.

Patient Name:

Address:

Contact Number:

E mail:

Signature: Initial:

Full name signature:

Annexure 2: Feedback form for doctor/nurse

Name of patient:

Date:

Doctor /Nurse name

Group: MAD / CTB

Procedure:

Parameter	Points (0-2)
Comfort level	
Complexity of the application	
Hygienic quality and impression	
Post procedure cloth staining	
Haemostatic and sealing efficiency	
Total	

Remarks:

Signature: