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Effect of Povidone-Iodine Dressings on Surgical Site Infection Rate: A Randomised Controlled Trial

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Abstract

Many different dressings can be used following breast cancer operations. There is no definite standard with regard to which dressing is superior. This study aimed to compare Povidone-Iodine dressing against dry dressing for the rates of infection and difference in wound healing. A single-centre, double-blinded, randomised controlled trial was conducted between October 2014 and May 2015 after obtaining ethical approval. The patients were randomised into two groups. One group had their wound dressed with steristrips, dry blue gauze and clear water-proof dressing. The other group had the same dressing except that the blue gauze was soaked in Povidone-Iodine. The results demonstrated that there is no statistical difference in reduction of post-operative infections by using Povidone-Iodine soaked dressing. There was no delay in wound healing in either group. We suggest that further larger multi-centre RCTs will help in further evaluating its routine use.

Key Words

Breast cancer; Surgical Site Infection; RCT; Povidone-Iodine dressing; Wound healing.

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Introduction/Aims

Although the incidence of infection after breast cancer surgery is low, any infection can delay adjuvant treatment.

There are many different dressings that can be used following breast cancer operations. There is no definite standard with regard to which dressing is superior. The aim of the study was to compare Povidone-Iodine dressing against dry dressing for the rates of infection and difference in wound healing.

Method

We conducted a single-centre, double-blinded, randomised controlled trial between October 2014 and May 2015 after obtaining ethical approval. Patients who underwent breast cancer surgery under the care of a single onco-plastic consultant were included in this study. The patients were randomised into two groups. One group had their wound dressed with steristrips, dry blue gauze and clear water-proof dressing. The other group had the same dressing except that the blue gauze was soaked in Povidone-Iodine. The randomisation was done before the surgery by the nursing staff by drawing a sealed envelope with either number "1" or number "2" inside the envelope. Number "1"

indicated that the patient would have Povidone-Iodine dressing and number "2", a dry dressing.

An information leaflet (appendix 1) was given to the patient who agreed to participate in the study and informed consent (appendix 2) was obtained.

Operating surgeons and patients were blinded to the type of dressing to be used. The operating surgeon, went out of the theatre after wound closure and randomisation of the dressing and the application of the dressing was done by theatre nursing staff and the foundation year doctor after that. The dressing was covered with non-transparent white foam dressing to ensure further blinding of the surgeons as well as the patients. Postoperative follow up included a 2-4 week outpatient clinic where the clinical nursing staff would remove the dressing before the surgeon could comment on the wound site. Surgical site infection, if any, was recorded. The patient records were reviewed for returns to theatre and re-admissions. The data was then compiled and analysed.

Diabetic patients, patients who took oral steroids or who had been treated with chemotherapy 3 months prior to the procedure, allergic to iodine,

Procedure	Group 1 (not infected)	Group 1 (infected)	Group 2 (non-infected)	Group 2 (infected)
Mastectomy	12	0	9	0
Wide Local Excision	10	0	9	1
Sentinal Node Biopsy Only	2	0	3	0
Axillary Clearance Only	3	0	1	0
Axillary Node Biopsy	0	0	2	0
Duct Excision	1	0	0	0
Fibroadenoma Excision	0	0	2	0
Removal of Implant	0	0	1	0
TOTAL	28	0	27	1

with reconstruction following breast cancer surgery and immuno-compromised were excluded from the study.

Results

A total number of 56 patients participated in the study. 28 patients were in each arm following randomisation. There were 9 broad operation subtypes. The most common operation type performed was a mastectomy, forming 36% of the total data.

Only one patient who partook in the study suffered a minor wound infection. This patient was in group 2, so had a dry dressing. No patients in group 1 suffered a post operative wound infection. Statistical analysis showed the $p=0.31$, which means there was no significant difference for infection risk between the two groups. Therefore, there is no significant advantage to reduce infection rates in either dressing used. There was no case of delayed wound healing in either of the groups. There were no readmissions or returns to theatre due to wound infection or any other complications in either of the groups. The results are summarised in Table 1:

Discussion:

The use of Povidone-Iodine perioperatively to reduce infection rates has been a contentious issue. Often it depends on surgical preference, and there is no concrete evidence to support or go against its use.

The literature search was conducted via NHS

Athens evidence website, and an advanced healthcare database search was conducted. The search included the following databases: Medline via HDAS, Medline via Pubmed and Google Scholar. The search was conducted on 2nd November 2015.

We used the following search terms: Iodine, Breast, Gauze, Dressing, Bandage, Post-operative, and Infection.

We found a total of 7 papers which were of interest. From these 7, only one was breast surgical specific, however, this was a RCT looking at Povidone-Iodine versus Chlorhexadine in skin antisepsis for elective plastic surgical procedures. They noted that staphylococcal skin colonisation was lower at the end of surgery when Chlorhexidine 0.5% was used; however, this was not significantly lower compared to Povidone-Iodine.¹

There were two papers which stated that Povidone-Iodine antisepsis was effective at reducing post-operative infection rates. In the first paper, sixty-three patients with central tympanic membrane perforation were enrolled in the study, and the external auditory canal was packed with Povidone-Iodine. They noted that this was an effective method for eliminating pathogenic bacteria for tympanoplasty.² Benson et al looked into dual application versus single application of Povidone-Iodine in strabismus surgery, and concluded that a second application of Povidone-Iodine significantly decreased the rate of contamination of the surgical

site and sutures.³

There were studies which were against the use of povidone-iodine. Povidone-iodine in reducing post-operative surgical site infections. Walker et al conducted a prospective RCT for patients undergoing varicose vein surgery. He did not find a significant reduction in post-operative infection rate for Povidone-iodine soaked swabs when compared to saline soaked swabs.⁴ Even for post-operative hand abscess infection rates were not significantly reduced when patients received Povidone-iodine soaks 3 times daily versus daily dressing changes.⁵ The final two papers agreed that there is a lack of evidence to support the use of iodine soaked swabs to reduce perioperative infection rates and that this warrants further RCT.^{6,7}

From the above reported literature, it is clear that there is a lack of data supporting or going against the use of Povidone-iodine to reduce post operative infection rates. There are no studies looking specifically at its use in breast surgery when comparing it to a plain dressing.

Limitations of our study:

We acknowledge the small sample size of this study. Further studies with larger sample sizes should be conducted.

Conclusions:

Our RCT shows that there is no statistical difference in reduction of post-operative infections by using Povidone-iodine soaked dressing. There was no delay in wound healing in either group. We feel that further larger multi-centre RCTs will help in further evaluating its routine use.

References:

1. Veiga DF, Damasceno CAV, Veiga-Filho J et al. Povidone Iodine versus Chlorhexadine in Skin Antisepsis before Elective Plastic Surgery Procedures: A Randomised Controlled Trial. *Plastic and Reconstructive Surgery*. 2008;124:340-342.
2. Bacterial change in external auditory canal upon antisepsis with povidone-iodine during tympanoplasty. *European archives of oto-rhino-laryngology*. 2015;272:551-555.
3. Dual application versus single application of povidone-iodine in reducing surgical site contamination during strabismus surgery. *Journal of AAPOS*. 2014;18:347-350.
4. Randomised, blinded study to assess the effect of povidone-iodine on the groin wound of patients undergoing primary varicose vein surgery. *ANZ journal of surgery*. 2013;83:844-846.
5. Povidone-iodine soaks for hand abscesses: a

prospective randomized trial. *The Journal of Hand Surgery*. 2014;39:962-965.

6. Limb wounding and antisepsis: iodine and chlorhexadine in the early management of extremity injury. *The international journal of lower extremity wounds*. 2012;11:213-223
- Interventions for preventing infectious complications in haemodialysis patients with central venous catheters. *The Cochrane database of systematic reviews*. 2010.

Appendix I: information leaflet

PARTICIPANT INFORMATION SHEET

TITLE OF STUDY: Effect of Povidone-Iodine dressings on surgical site infection rate.

NAME OF RESEARCHERS: Mr A Deshpande, Miss Layin Lim, Dr Kohei Matsumoto, Dr Saleem Mastan and Dr Rosie Harkness.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with us if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

To see whether using a liquid called 'povidone iodine' on the dressings that you have following surgery may reduce the risk of infection at the site of surgery.

Why have I been chosen?

You have been chosen because you are having breast surgery and we would like to look at infection rates following breast surgery. We will invite all patients that Mr Deshpande and team operate on in the next three months to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time or a decision not to take part will not affect the standard of care you receive in the long term.

What will happen to me if I take part?

Following your surgery you will have a dressing put on your breast which will either be a plain dressing or one containing povidone iodine. You will not be told which type you have been given. You have are

equally likely to be given a simple dressing as you are a povidone iodine one. It is a 50% chance of each.

2-3 weeks later you will be followed up **as normal** in the clinic and the breast surgery site will be examined. If you **are** taking part, then the doctors opinion of whether the wound has become infected or not will be recorded for the study. Whether you are taking part or not, any infection will be treated. No normal treatment will be withheld from any person.

Different surgeons use iodine dressings or plain dressings depending on their preference. We are therefore not doing anything different to you than what is already happening in breast surgery. We are simply looking at the difference between the two options.

This trial will be a 'double-blind trial' which means that neither you nor the surgeon will know if you have received a simple dressing or a povidone-iodine dressing. Only the nurses will know. This makes our results more accurate. You will be randomly assigned a dressing out of the two options.

What do I have to do?

You do not have to do anything except to allow the surgical site to have a dressing put on it. If you do not take part, you will still be given a dressing, but the results will not be included in the study.

What is the drug or procedure that is being tested?

It is called povidone iodine. It is generally used as an antiseptic and is used for cleaning wounds.

What are the alternatives for treatment?

The two alternatives are having a dressing which contains povidone- iodine and having a plain dressing. You cannot choose which one you would like if you take part in the study.

What are the side effects of any treatment received when taking part?

Povidone iodine is a very simple liquid which only very rarely causes side-effects. The only risk is that you may have an allergic reaction to the povidone iodine. This could be a simple rash and discomfort or a reaction that causes problems with your breathing and your throat to swell. You would be treated for both of these reactions in the unlikely event that an allergy had occurred. If you are known to be allergic to the iodine, we will not enrol you into the study.

What are the possible disadvantages and

risks of taking part?

Any procedure has risks and these will be fully explained to you. As stated above, the main risk of taking part is an allergic reaction to povidone iodine but this rarely happens.

What are the benefits of taking part?

The research may benefit you or future patients because the findings will inform treatment in the future. It may lead us to discover that using povidone iodine makes it less likely for a surgical wound to be infected. We would then use this rather than a simple dressing. We may find that it makes no difference and only use simple dressings.

What if new information becomes available?

We will inform you if any new information becomes available while you are taking part in the study.

What happens when the research study stops?

You will be continued to be cared for under standard treatment by the NHS

What if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanism should be available to you.

Will my taking part in this study be kept confidential?

All information, which is collected, about you during the course of this research will be kept strictly confidential. Any information about you, which leaves the hospital, will have your name and address removed so that you cannot be recognized from it. If a scientific paper is written about the results your name and details will be removed completely.

What will happen to the results of the research study?

The results of the study might be published at meetings or perhaps in a scientific paper.

Who is funding this study?

This study does not require funding as it is simply looking at something that already happens in hospital.

Who has reviewed this study?

The NRES committee West Midlands, Coventry and Warwickshire have reviewed this study.

Contact for further information.

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Rosie Harkness: rosie.harkness@doctors.org.uk
If you would like some general information about being involved in a research project please contact your local Research & Development Department on 01257 256465 or see www.nres.org.uk or www.involve.org.uk

Alternatively you can contact the local hospital PALS patient.relations@wvl.nhs.uk
PALS Manager, Trust HQ, Wigan Lane, Wigan, WNI 2NN telephone number 01942 82 2376 if you have any comments.

Thank you for taking the time to read about this study, if you have any questions please do not hesitate to ask. If you agree to take part you will be given a copy of this information sheet as well as the consent form for taking part in the study.

Appendix 2: Consent form

PARTICIPANT CONSENT FORM

Centre Name: Royal Albert Edward Hospital

Study Number: IRAS ID: I63407

Patient Identification Number for this trial:

Title of Project: Effect of Povidone-Iodine dressing on surgical site infection rate.

Name of Researchers: Mr A Deshpande, Miss Layin Lim, Dr Kohei Matsumoto, Dr Saleem Mastan, Dr Rosie Harkness.

Please initial box

I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from the trust, or from regulatory authorities, where it is relevant to my taking part in this research, I give permission for these individuals to have access to my records also my GP will be notified.

I agree to take part of the above study

Name of Patient	Date	Signature
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Name of Person taking consent	Date	Signature (if different From Researcher)
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Researcher	Date	Signature
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