Preoperative antibiotic prophylaxis in mastectomies related to postoperative infections

Version 2

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Abstract

Introduction
Breast cancer is a very common malignancy among women. Surgical removal of the tumor is often the first choice of treatment. Mastectomy is a routinely performed surgery and have a reported frequency of postoperative infections between 3-15%. The department of surgery university hospital, Örebro, Sweden changed their routines 2012 and started treating all patients going through a mastectomy with preoperative antibiotic prophylaxis.

Objective
The aim with this study was to investigate if preoperative antibiotic reduced the risk of evolving a postoperative infection after mastectomies. Consequently the new routines to administer preoperative antibiotic to women going through mastectomies can be evaluated.

Method
128 patients were included in this observational study, 64 had received preoperative antibiotic and 64 had not. The charts were surveyed 30 days postoperatively and postoperative infections were recorded.

Results
A total of 10/128 patients evolved a postoperative infection. This study found a RR=0.43 (p=0.19) in favor of antibiotic when comparing the two groups. When only investigating modified radical mastectomy this study found a RR=0.38 (p=0.32) in favor of antibiotics. Aspiration of seroma fluid was associated with a higher incidence of postoperative infection.

Conclusion
The results suggest that preoperative antibiotic may have protective effects on patients going through mastectomies. However the results failed to find statistical significance and therefore more extensive studies are needed to be able to evaluate the new routines of preoperative antibiotic in mastectomies at department of surgery, university hospital, Örebro, Sweden.

Keywords: Prophylactic antibiotic, mastectomy, postoperative infection
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1. Introduction

1.1 Breastcancer

Breastcancer is one of the most common malignancies in the world. With an incidence of one million per year it’s the most common malignancy in women and accounts for 18 % of all cancer in women [1]. The etiology of breast cancer is suggested to be multifactorial. Established risk factors are a high lifetime exposure to estrogen such as early menarche and late menopause [1]. Malignant breast neoplasm arise through a series of stepwise accumulations of genetic mutations [2]. Evidence support two major types of precursor lesions, most commonly ductal carcinoma in situ (DCIS) which give rise to invasive ductal cancer, and lobular carcinoma in situ (LCIS) which may progress to invasive lobular cancer. Another important part in the tumorgenesis is the nonneoplastic cells, such as fibroblast and inflammatory cells of the breast and their interaction with the tumortransformed cells [2].

Breastcancer is a very heterogeneous disease and the most important preoperative prognostic factors are tumorsize, lymphnode or distant metastases. These aspects also determine which kind of treatment that’s most appropriate. Other factors important for the progression of the tumor is if the tumourcells are responsive to estrogen, progesterone or are HER2-receptor positive. [3]

Since breast cancer most often are asymptomatic in its early stages it can be difficult to diagnose. The most commonly used diagnostic methods are clinical evaluation including palpation, mammography and biopsies. Investigation on mammography has showed that screening can reduce mortality rate in women aged 39-69 [4]. Still breast cancer is the leading cause of death in women aged 40-50 [1].

1.2 Mastectomies and postoperative infections

Mastectomy is a routinely performed surgery and often the first treatment for breastcancer. The procedure is referred to as a clean surgical procedure, defined as a surgery where no infected organ or organ containing microbiota is perforated. There are two main types of mastectomies performed: 1) total (simple) mastectomy with or without sentinel node biopsy. 2) MRM (Modified radical mastectomy), which along with removal of the entire breasttissue also includes an axillary dissection, but preserving the m.pectoralis major [5].
Postoperative wound infections is a major complication to surgery. The frequency of postoperative wound infections related to mastectomies is reported to be between 3-15% [6]. Most commonly the infection presents as a superficial skin or subcutaneous infection. The most common etiologies are *Staphylococcus aureus* and *Escherichia coli* [7].

Fewer postoperative infections decrease patients suffering as well as shortening health care visits [8]. A postoperative infection may also delay further treatment such as radiation or chemotherapy. It is well known that a greater use of antibiotics may cause more resistant bacterial colonies.

Seroma formation, the development of a sack of clear, serous fluid underneath the skin postoperatively is a common complication to mastectomies, the incidence is reported to be somewhere between 15-85% of patients going through mastectomies [9]. After an axillary dissection the surgeon decides if there is a need of an active drainage to be placed in the axillary wound to drain the lymphatic fluid normally drained by the lymphatic vessels. A systematic review published 2011 comparing six Randomized controlled trials with a total number of 585 patients did find a statistically significant difference in frequency of seromas, total volume of seromas and number of aspirations, related to if drainage were used or not but it did not find a statistically significant difference in the frequency of postoperative wound infections related to if a drainage were used or not [10].

1.3 Antibiotic prophylaxis used in mastectomies

Several randomized, double-blinded, placebo-control studies suggest that there is no significant difference between antibiotic prophylaxis and placebo regarding the frequency of postoperative surgical site infections in mastectomies [11], [12], [13]. One study randomized 254 women going through a modified radical mastectomy, the intervention was 1 g cefazolin intravenously 30 minutes prior to skinincision. The infection rates declined from 15% to 13.4% in the intervention group, results not statistically significant [11]. One study also included patients going through local excision and microdochectomy (removal of the *ductus lactiferi*) as well as mastectomy and did not find a statistical significant different when 2 g flucloxacillin were intravenously administered at time of induction of anesthesia [13].
The use of preoperative antibiotic prophylaxis may have positive effects in reducing the frequency of postoperative surgical site infections (SSI). According to a recently published meta-analysis on the topic that compared 9 RCTs, (Randomized clinical trials) there were a statistically significant reduction in the frequency of postoperative infections after mastectomies when preoperative antibiotic prophylaxis were administered. A total of 3720 patients were included and the meta-analysis found a RR (0.64; 95% CI, 0.50-0.83) when comparing all antibiotic groups with placebo. [14].

The SBU of Sweden presented a report in August 2010 about preoperative antibiotic prophylaxis in mastectomies that declared a strong evidence for that antibiotic prophylaxis significantly reduced the risk of postoperative infections [15]. This report relied on 2 meta-analyses [16], [17]. One of these Meta-analysis comparing 6 RCTs, a total of 1924 patients found a pooled RR=0.66, (95% CI, 0.48 to 0.89) when comparing preoperative antibiotic and placebo groups and the conclusion was that administering preoperative antibiotic prophylaxis lowers the risk of evolving a postoperative infection in patients going through mastectomies [17].

The department of surgery on the university hospital, Örebro, Sweden changed their routines and started to treat all patients going through a mastectomy with one preoperative peroral dose of Eusaprim® forte 160 mg/800 mg administered the morning of surgery day with start the year of 2012.

1.4 Objective
The aim with this retrospective observational study was to investigate the relationship between preoperative antibiotic prophylaxis in patients undergoing mastectomy and the frequency of postoperative infections. By comparing patients who have received preoperative antibiotic prophylaxis with them who have not, the new routinely use of preoperative antibiotic prophylaxis in mastectomies performed at the department of surgery at university hospital, Örebro, Sweden can be evaluated.
2. Material and Methods

2.1 Studydesign

This observational study investigated women going through a simple mastectomy (operation code HAC20) with or without sentinel node biopsy or a modified radical mastectomy (operation code HAC22) at the department of surgery at university hospital Örebro, Sweden. To achieve two different groups, one where preoperative antibiotic had been administered and one where no antibiotic prophylaxis had been given, the survey investigated women going through surgery the year of 2011 when no preoperative antibiotic were given as a routine as well as the year of 2013 when routines had changed and all women were receiving preoperative antibiotic prophylaxis.

The charts of these patients were surveyed in aspects of age, current smoking, BMI (body mass index), the occurrence of another malignancy, diabetes, some kind of immunosuppression (HIV, immunosuppressive medication), if preoperative chemotherapy or radiation treatment had been administered, which kind of mastectomy had been performed, and most important if preoperative antibiotic prophylaxis had been administered.

2.2 Subjects

A total of 79 women went through simple or modified radical mastectomy between 2011-04-19 and 2011-12-13 at the department of surgery, university hospital, Örebro, Sweden. All charts where investigated and a total of 16 patients were excluded: 8 because of lack of documentation whether or not antibiotic had been administered. 1 because of follow-up at another hospital and 7 because of a different way of administering antibiotic prophylaxis, example 5 consecutive days postoperatively. 63 patients where included in the “no antibiotic group”. See figure 1.

![Figure 1. Flowchart over included and excluded patients.](image-url)
Between 2013-01-03 and 2013-09-10 a total of 75 patients went through a simple or modified radical mastectomy. All charts were surveyed and 10 patients were excluded: 1 because of lacking documentation. 5 because of follow-up at another hospital and 4 because of a prolonged preoperatively administered antibiotic prophylaxis. 1 out of the 75 patients in this group did not receive preoperative antibiotic because of mistakes and were included in the “no antibiotic group”. A total of 64 patient where included in the “antibiotic group” where the inclusion criteria were that one dose of pre or perioperative antibiotic where administered. With seven exceptions (because of allergy to sulfa, mistakes made by healthcare workers) all patients were receiving a peroral dose of Eusaprim ® forte 160 mg/800mg. See figure 2. A total of 128 patients where included, 64 in each group.

Figure 2. Flowchart over included and excluded patients.

2.3 Outcome
The charts where surveyed 30 days postoperatively to investigate if the patient had a wound infection related to the surgery. The definition of a postsurgical wound infection in this study were: Either 1) an infection verified by microbiological cultivation or 2) a clinical infection where the treating doctor prescribed antibiotic treatment, both within 30 days postoperatively. To investigate if evolving of seroma and the number of punctuation affected infection rates,
the charts were also investigated in the aspects of seroma formation within 30 days postoperatively as well as number of aspirations of seroma fluid.

2.4 Statistics
All data were collected in excel 2010. Since all results were binary and unpaired, p-values were calculated with chi-2-test in excel.

2.5 Ethics
All data in this observational study is handled anonymously and no information from specific patients will be presented. The survey were done by investigating charts of patients who were not informed. This study was performed as a quality-work and therefore no ethical approval was required.

3. Results

3.1 Group characteristics
Because of deficient documentation on all patients regarding smoking habits and BMI these aspects cannot be compared between the groups. None of the 128 patients were immunosuppressed defined by HIV infection or immunosuppressive medication.

The mean age of all included patients were 64,9 years of age with a range from 30-96 years. Group number 1 which had not been receiving antibiotic had a mean age of 64,7 (range 30-96), compared with a mean age of 65,1 (range 31-90) in group number 2.

In group 1, 11 patients had a history of another malignancy, compared with 16 in group 2.
The frequency of diabetic patients in group number 1 was three, and in group number 2 there were nine patients with diabetes.

None of the patients in group number 1 had preoperative radiationtherapy for their breastcancer. Four patients in group number 2 had received radiationtherapy prior to their surgery, one patient for ovarian cancer, one for colorectal cancer and two patients received preoperative radiationtherapy for breastcancer in the contralateral breast, all within one year prior to their mastectomy. The number of patients that had preoperative chemotherapy for their breastcancer was six in each group.
Out of all the 128 patients, 79 went through a simple mastectomy with or without sentinel node biopsy (HAC20) and 49 went through a modified radical mastectomy (HAC22). The distribution of different types of surgery in each group were: In group 1, 35 had simple mastectomy and 29 had a MRM, in group number 2, 44 patients went through a simple mastectomy and 20 patients had a MRM. The most important group characteristics can be seen in table 1.

Table 1. Group Characteristics

<table>
<thead>
<tr>
<th></th>
<th>No Antibiotic group</th>
<th>Antibiotic group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>N=64</td>
<td>N=64</td>
</tr>
<tr>
<td><strong>Age (years)(range)</strong></td>
<td>mean age = 64,7 (30-96)</td>
<td>mean age = 65,1 (31-90)</td>
</tr>
<tr>
<td><strong>Preoperative chemotherapy</strong></td>
<td>N=6</td>
<td>N=6</td>
</tr>
<tr>
<td><strong>Simple mastectomy</strong></td>
<td>N=35</td>
<td>N=44</td>
</tr>
<tr>
<td><strong>Modified radical mastectomy</strong></td>
<td>N=29</td>
<td>N=20</td>
</tr>
</tbody>
</table>

3.2 Postoperative Infections

The total incidence of postoperative infections within 30 days from surgery was 10/128 (7.8%). 3 out of these infections was defined as a positive microbial culture and seven were a clinical infection where the treating doctor prescribed antibiotic treatment on the basis of clinical manifestations. The frequency of postoperative infections in the no antibiotic group was 7/64 (10,9%) compared with 3/64(4,7 %) in the antibiotic group RR= 0,43 (in favor of antibiotic). (p= 0,19). The calculated odds ratio was OR=0,43 in favor of antibiotic. Results is shown in table 2.

Table 2. Frequency of postoperative infections

<table>
<thead>
<tr>
<th></th>
<th>No antibiotic group n=64</th>
<th>Antibiotic group n=64</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total number of postoperative infections</strong></td>
<td>N=7 (10,9%)</td>
<td>N=3 (4,7%)</td>
</tr>
<tr>
<td><strong>Infections defined as a positive microbial culture</strong></td>
<td>N=3</td>
<td>N=0</td>
</tr>
<tr>
<td><strong>Infections defined by treating doctor based on clinical evaluation</strong></td>
<td>N=4</td>
<td>N=3</td>
</tr>
</tbody>
</table>
3.3 Type of surgery

Out of the 128 patients, 79 went through a simple mastectomy and 49 went through a MRM. 44/79 patients that went through a simple mastectomy received preoperative antibiotic compared with 20/49 patients that went through a MRM. When comparing the type of surgery related to postoperative infections it shows that 10,2% of all patients going through a MRM acquired a postoperative infection compared with 6,3% of patients going through a simple mastectomy. The RR when comparing simple mastectomy and MRM was RR=0,62.(p= 0,43) in favor of simple mastectomy and the odds ratio was OR=0,62. See table 3.

Table 3. Postoperative infections when comparing type of surgery

<table>
<thead>
<tr>
<th></th>
<th>Simple mastectomy n=79</th>
<th>Modified radical mastectomy n=49</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number receiving preoperative antibiotic</td>
<td>N=44 (55,7%)</td>
<td>N=20 (40,8 %)</td>
</tr>
<tr>
<td>Frequency postoperative infections</td>
<td>N=5 (6,3%)</td>
<td>N=5 (10,2%)</td>
</tr>
</tbody>
</table>

When furthering examining the results of the different types of mastectomies and creating 4 different groups depending on which surgery they went through as well as if they received preoperative antibiotic or not, this results were found: Of the total 79 patients going through a simple mastectomy 44 had received preoperative antibiotic and 35 had not. Two of the 44 patients (4,8%) receiving preoperative antibiotic evolved a postoperative infection compared to three of the 35 (8,6%) that had not received antibiotic prophylaxis. This gives a RR=0,56 in favor of antibiotics (p=0,47).

Out of the total 49 patients going through a MRM 20 had received preoperative antibiotic and 29 had not. One of the 20 (5,3%) patients in the antibiotic group developed a postoperative infection compared with four out of 29 (13,8%) in the no antibiotic group. The calculated RR= 0,38 (p=0,32) in favor of antibiotic. Results can be seen in table 4.
Table 4. Postoperative Infections in aspects of type of surgery and preoperative antibiotic

<table>
<thead>
<tr>
<th></th>
<th>Patients not developing a postoperative infection.</th>
<th>Patients developing a postoperative infection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple mastectomy (HAC20) (n=79)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Receiving preoperative antibiotic (n=44)</td>
<td>N=42</td>
<td>N=2 (4,8%)</td>
</tr>
<tr>
<td>- No antibiotic (n=35)</td>
<td>N=32</td>
<td>N=3 (8,6%)</td>
</tr>
<tr>
<td>MRM (HAC22) (n=49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Receiving preoperative antibiotic (n=20)</td>
<td>N=19</td>
<td>N=1 (5,3%)</td>
</tr>
<tr>
<td>- No Antibiotic (n=29)</td>
<td>N=25</td>
<td>N=4 (13,8%)</td>
</tr>
</tbody>
</table>

3.4 Formation of seroma

A total of 47 patients evolved postoperative seroma within 30 days from surgery. 33 of these patients required punctuation and aspiration of seroma fluid. Consequently 14 patients evolved seroma not large or disturbing enough to demand punctuation. Of those 33 patients evolving seromas large enough to demand punctuation 12 had gone through a MRM and 21 had gone through a simple mastectomy, 19 patients had received preoperative antibiotic and 14 did not. Out of the 33 patients four developed a postoperative infection (12,1%).

The total number of patients not evolving seroma or evolving seroma not large enough to indicate punctuation was 95. Out of these patients 58 had gone through a simple mastectomy and 37 had gone through a MRM. 45 of the 95 patients had received preoperative antibiotic and 50 had not. Six patients evolved a postoperative infection (6,3%). When calculating relative risk in the aspects of if seromaformation gives more frequent postoperative infections the RR= 1,92 (p=0,28) when aspiration of seroma fluid is viewed as a risk factor. See table 5.

Out of the 33 patients evolving a seroma large enough to need an aspiration, a majority needed one to three aspirations and two patients required more than three aspirations. Of the four patients that acquired a postoperative infection as well as postoperative seroma formation three patients had only one aspiration of seroma fluid and one had eight aspirations of seroma fluid.
Table 5. Comparing seroma punctuation and the risk of evolving a postoperative infection.

<table>
<thead>
<tr>
<th></th>
<th>Patients not evolving seroma or developed seroma not needing aspiration n=95</th>
<th>Patients evolving seroma and aspiration of seroma fluid n=33</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients receiving preoperative antibiotic</td>
<td>N=45 (47,4%)</td>
<td>N=19 (57,6%)</td>
</tr>
<tr>
<td>Patients going through a MRM</td>
<td>N=37 (38,9%)</td>
<td>N=12 (36,4%)</td>
</tr>
<tr>
<td>Patients evolving a postoperative infection</td>
<td>N=6 (6,3%)</td>
<td>N=4 (12,1%)</td>
</tr>
</tbody>
</table>

4. Discussion

This observational study investigated 128 patients going through a simple or modified radical mastectomy at the department of surgery, university hospital, Örebro, Sweden. The total incidence of postoperative infections within 30 days postoperatively were 10/128 (7,8%) which is in within the reported range of 3-15% [6]. This results is not surprising but implies that the department of surgery, university hospital, Örebro, Sweden is comparable with the general departments around the world in aspects of postoperative infections.

When comparing the 64 patients that had received a peroral dose of Eusaprim ® Forte preoperatively with the 64 patients that had not received preoperative antibiotic the incidence of postoperative infections declined from 10,9% in the “no antibiotic group” to 4,7% in the antibiotic group, the calculated relative risk was RR=0,43 in favor of antibiotics. This results may suggest that preoperative antibiotic may reduce the incidence of postoperative infections in patients going through mastectomies. However this study did not find a statistical significant reduction in the incidence of postoperative infections (RR=0,43 (p=0,19)). The group characteristics is very much comparable in all aspects except type of surgery where far more patients in the no antibiotic group went through a MRM which may influence the results since MRM is proposed to be associated with a higher risk of postoperative infections. Several existing RCTs have also failed to find a statistically significantly risk reduction in the incidence of postoperative infections when preoperative antibiotic where administered [11], [12], [13], [18].
This study investigated two different types of mastectomies: simple mastectomy and the more complicated modified radical mastectomy. When comparing infection rates depending on type of surgery this study found a risk reduction in aspects of postoperative infections when antibiotic prophylaxis were used in both types of surgeries. In patients going through a simple mastectomy the incidence of postoperative infections were 3/35 (8.6%) in the “no antibiotic group” and declined to 2/44 (4.8%) in the group that had received preoperative antibiotic. When only investigating MRMs and comparing if antibiotic had been given preoperative or not this study found a RR= 0.38 in favor of antibiotic. This suggest that patients going through a MRM are at higher risk of evolving a postoperative infection, this may be attributable to the insertion of an active drainage or a more extensive surgery wound. The aspects of drainage usage and the impact on postoperative wound infection is somewhat controversial, one study suggest that there is no significant difference between usages of drains in aspects of postoperative infections [19]. On the other hand one study that have surveyed the use of active drains and antiseptics conclude that use of antiseptics can reduce the frequency of drain associated infections [20]. The utilization of active drains was not investigated in this study, even though it may influence the risk of postoperative infections and the local routines of how to handle the drains may influence the risk. The result in this study suggest that patients going through a MRM may have better benefit from preoperative antibiotic than patients going through a simple mastectomy. Even in the aspects of different kind of surgery this study failed to find results statistically significant.

The formation of seroma after mastectomies is a well-known postoperative adverse effect. This survey found that 33/128 (25.8%) of the patients evolved seroma large enough to demand punctuation and aspiration of seroma fluid, which is in the lower part of the reported international incidence of 15-85%[9].

A plausible theory is that a MRM remove more lymphatic tissue and therefore predisposes to seroma formation. The type of surgery did not seem to influence the incidence of seroma formation since approximately 37% in both groups went through a MRM in this study. When comparing MRM to other kind of mastectomies, MRM is shown to elevate the risk of seroma formation [21]. The aspect of active drainage placed in the axillary wound was not studied in this survey and therefore no conclusion can be made. One study on the topic concludes that insertion of an active drainage does not raise the risk of a postoperative infection [22]. The results in this study suggest that evolving of seroma and aspiration of seroma fluid is a risk
factor for developing a postoperative infection since the patients that evolved a seroma in
general had received more preoperative antibiotic and still developed more postoperative
infections. However these results are not statistically significant and larger studies are needed
to make a scientific conclusion. The data of number of aspirations of seroma fluid were too
limited to make any discussion on the topic, even though it’s an interesting question if more
frequent aspirations of seroma fluid increase the risk of postoperative infections. Two factors
that may be discussed on the topic is that the more unstable seroma tissue in combination of
incision of a foreign object to aspirate the fluid may increase the risk of infection.

This study investigated the use of a peroral dose of Eusaprim ® Forte 160 mg/800 mg as
preoperative antibiotic prophylaxis. The majority of published RCTs have used another kind
of antibiotic and mostly intravenous administration. A recently published Cochrane-review on
the topic could not conclude which kind of preoperative antibiotic that preferably should be
used in mastectomies [6]. Eusaprim antagonizes the bacteria’s production of folic acid which
is an essential metabolite in the purine metabolism and therefore cell division. Eusaprim have
the advantages that it has high biological availability, relatively broad bacterial spectrum, long
plasma half-life and is not the first choice of antibiotic treatment if a postoperative infection
would appear [23]. This study did not investigate different kinds of antibiotics and therefore
cannot discuss the question which antibiotic should be used even though it’s an interesting
question for clinical practice.

Using preoperative antibiotic can be controversial because of a series of adverse effects such
as allergic reactions and clostridium difficile-associated diarrhea in patients and more resistant
bacterial colonies in the hospital environment. These adverse events are very important to
take in mind when discussing prophylactic antibiotics, these aspects were not investigated in
this study and can therefore not be discussed between the groups. Cost-effectiveness is also an
important aspect to take in mind when initialing new routines, however this study did not
investigate this matter.

The clinical significance of this study is limited due to the weak statistic results and one
important factor for this is the relatively small number of patients studied. The fact that this is
an observational study based on chart survey may also influence the results according to
deficient documentation.
5. Conclusion

The results in this observational study suggest that preoperative antibiotic may have protective effects on patients going through mastectomies related to the development of postoperative infections. The results however failed to find statistical significance and therefore the conclusion is that more extensive studies are needed to be able to evaluate the new routines of preoperative antibiotic in mastectomies at department of surgery, university hospital, Örebro, Sweden.

6. Acknowledgements

I would like to give a special thanks to Göran Wallin for the idea of study design and the opportunity to implement this study. I would also like to thank my head supervisor Maria Wedin for all help throughout the process, data collection as well as writing process. Last but not least I would like to thank Marianne Janmark, administration personnel at the department of surgery for all practical help with my data collection.
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