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Research Project Plan RP10-01

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Title:

How to increase patient comfort during treatment with intravesical chemotherapy
- a randomized controlled trial

How to increase patient comfort during treatment with intravesical chemotherapy
- a randomized controlled trial

Introduction
Intravesical chemotherapy is used in patients who have undergone transurethral resection of the bladder (TUR-B) for non invasive (Ta) or superficially invasive (T1A / b) bladder tumors in which tumor is estimated to be of low risk type. Those patients are given a single instillation of mitomycin 40 mg dissolved in 40 ml. NaCl within the first 24 hours after TUR-B.
Superficial bladder tumours has a recurrence rate about 50% and relapse rate can probably be reduced by 40-50% at a single postoperative mitomycin installation
Mitomycin is a cytostaticum , which inhibits topoisomerase enzymes that are important for DNA synthesis during cell mitosis, thereby inhibiting neoplastic cell development.

As soon as possible after surgery when the patient's urine is cleared up and within 24 hours, the nurse instils Mitomycin into the bladder through a closed system. The patient should be on fluid restriction at least one hour before treatment. This to prevent urinary urgency during the two hour clamping of the catheter.

Patients complain of discomfort and pain during instillation including bladder spasms with severe urinary urgency. The solution with Mitomycin may leak by the side of the catheter. Often the patient can not manage to have the catheter clamped in 2 hours.

A small retrospective pilot study done in our unit showed that 7 out of 10 men and 2 out of 5 women had discomfort during the treatment. Two women received morphine-atropine-papavarine suppositories before the start of the treatment.

This project is a study of the clinical effectiveness of two instillation methods with the nurse administrated intravesical chemotherapy (Mitomycin) in patients with superficial bladder tumors.

Objective
The aim of the study is to examine the effect of elevation of the catheter bag compared to clamping the catheter. Simple elevation may reduce the discomfort during the postoperative treatment with intravesical of chemotherapy (Mitomycin) in these patients.

The following research questions will be answered
- examine the most effective way to install the Mitomycin with the least amount of discomfort for the patient
- how do the patient experience the Mitomycin instillation during the two methods
- will the patient be able to complete the entire treatment period of 2 hours
- will the patient be able to keep the Mitomycin in the bladder
- will it increase patient compliance

Endpoints of the study
Primary endpoint:
Comparison of patient discomfort between the elevated and clamped installation modalities expressed as differences in pain VAS-score

Secondary endpoints:
Comparison of fluid leakage between the two modalities
Comparison of installation time between the two modalities

Literature review
A study from 2005 showed that patients who received postoperative treatment with Mitomycin instilled into the bladder for two hours, and had elevated their urine bag instead of clamping the catheter had less bladder spasms and pain. (BJUI, Stoehr and Mueller, Innsbruck).

There are so far no other studies of the urologic patient experiences of discomfort and side effects during Mitomycin instillation.

Relevance to nursing
It is well known in clinical practice that patients suffer from discomfort when receiving intravesical chemotherapy. There are still limited data about how much the patients suffer from side effects and how the nurse can support the patients. There is no recommended standardisation of the method of instillation.
It is important to develop a new method to administrating the chemotherapy, which will increase the patients' compliance. First to gather information's on the problems prevalence and second to learn from patients' experiences and explore how a new methods can help decrease the patient's discomfort.

Methodology
The design is a open label prospective, randomized controlled study with an active group (the elevated installation modality) and an active concurrent control group (the clamped off installation modality).
The randomization will take place by random draw of sealed envelopes.
The patients will document discomfort in a questionnaire

Sample size 100 patients with 50 patients in each group. Patients are hospitalized and have undergone trans-urethral resection of the bladder (TUR-B) and subsequently treated with intravesical chemotherapy (Mitomycin).

Inclusion criteria
Men and women
Age > 18 years
Patients operated for expected non-invasive bladder tumor (Ta, T1)
Postoperative urine should be clear or pale rosé.

Exclusion criteria
Postoperative hematuria with clots 24 hours after TUR-B
Suspected bladder perforation.
Allergy to the Sub MAP
Allergy to Mitomycin.
Bladder catheter a demeure
Patients who can not understand information or can not cooperate

The patients meeting the in- and exclusion criteria will be asked to participate in the project. The patients who choose to participate in the trial will consecutively be selected and randomized 50 to intervention group and 50 to control group.

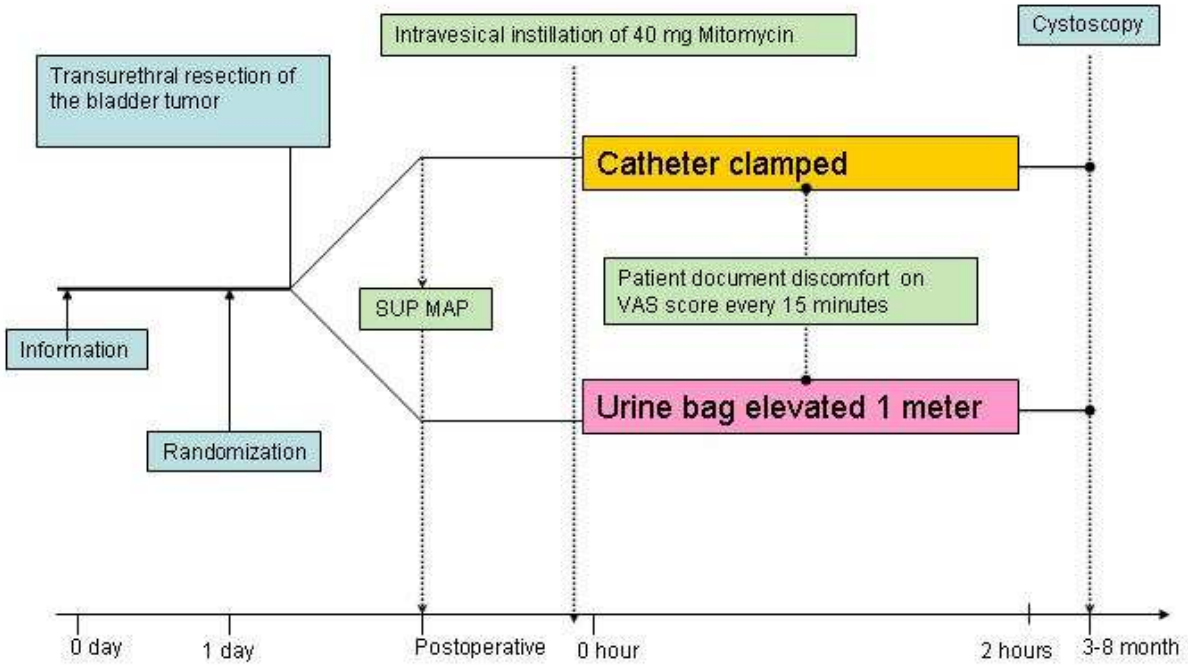
Treatment protocol:
Both groups will receive an intravesical instillation of 40 mg mitomycin C (Mito-extra ®, Medac to dilute in 40 ml distilled water), henceforth referred to as 'the medication' within 24 hours after surgery. Patients in both groups must remain in bed during treatment with an absorbent diaper under the pelvis. The medication is supposed to remain in the bladder for two hour but if the pain is intolerable for the patient the treatment will be stopped and the treatment time registered.
One suppository of morphine-atropine-papaverin. (MAP) is given to the patients in both groups prior to the instillation.

In the control group A, mitomycin will be instilled via a catheter and the catheter must be clamped for a maximum 2 hours

In the intervention group B, the catheter is not clamped but urine bag without reflux valve will be elevated 1 m above the superior iliac crista of the supine patient.
The hypothesis is that the elevated urine bag will enable bladder contractions with no rigid resistance. The mitomycins will retain within the bladder by hydrostatic pressure.

The patient will during treatment document in the questionnaire discomfort, pain, bladder spasm, urinary urgency and leakage of urine along the catheter every 15 minutes on a visual analogue scale (VAS, range 1-10).

The nurse documents the final time of surgery, duration of the instillation, pain medication given and measure the weight of the nappy and document a possible fluid loss.



The trial is not blinded as it is not practically feasible to construct a blinding device to mask the elevated bag, fluid movements and feel from the patients.

A pilot project will be done with 10 patients to ensure that the new technical approach is working and that the patient understands the questionnaire and the visual analogue scale.

Ethics
The study will be reported to the ethics committee for approval and the patient will be asked to give informed consent. In case any of them regret their participation, they can decide to leave the study immediately.

The project will be reported to the Data Protection Agency.

Timetable 2010

2010	Jan	Feb.	Mar.	April	Mai	June	July	Aug.	Sept.	Nov.	Dec.
Ethics Committee Approval											
Assembly of equipment											
Data collection Patient questionnaire											
Data analysis Results											
Implementation of new intervention program											
Publication											

Budget
Salaries:
Project nurse, 50 hours (24€/hour) = 1.200 €

Materials:
120 Sterile bags without reflux valve (7€ x 120) 840 €

Running costs:
Publication expenses (page charges, travelling) 1.000 €
Statistical counselling 500 €
Overhead 3.1% of total costs 110 €

Total **3650 €**

References
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Conflict of interest
None declared by the project participants