



Efficacy of preoperative uro-stoma education on self-efficacy after Radical Cystectomy; secondary outcome of a prospective randomized controlled trial



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ABSTRACT

Purpose: Radical Cystectomy with a creation of an uro-stoma is first line treatment in advanced bladder-cancer. Enhancing or maintaining an individual's condition, skills and physical wellbeing before surgery has been defined as prehabilitation. Whether preoperative stoma-education is an effective element in prehabilitation is yet to be documented. In a prospective randomized controlled design (RCT) the aim was to investigate the efficacy of a standardised preoperative stoma-education program on an individual's ability to independently change a stoma-appliance.

Methods: A parent RCT-study investigated the efficacy of a multidisciplinary rehabilitation program on length of stay following cystectomy. A total of 107 patients were included in the intension-to-treat-population. Preoperatively, the intervention-group was instructed to a standardized stoma-education program consisting of areas recognized necessary to change a stoma appliance. The Urostomy Education Scale was used to measure stoma self-care at day 35, 120 and 365 postoperatively. Efficacy was expressed as a positive difference in UES-score between treatment-groups.

Results: A significant difference in mean score was found in the intervention group compared to standard of 2.7 (95% CI: 0.9; 4.5), 4.3 (95% CI: 2.1; 6.5) and 5.1 (95% CI: 2.3; 7.8) at day 35, 120 and 365 postoperatively.

Conclusions: For the first time a study in a RCT-design have reported a positive efficacy of a short-term preoperative stoma intervention. Preoperative stoma-education is an effective intervention and adds to the evidence base of prehabilitation. Further RCT-studies powered with self-efficacy as the primer outcome are requested.

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1. Introduction

Radical Cystectomy (RC) with a subsequent creation of a urinary diversion remains the most comprehensive procedure in urology and first line treatment when diagnosed with muscle invasive bladder cancer (MIBC) or high grade non-muscle invasive bladder cancer (NMIBC) (Witjes et al., 2013).

Enhanced recovery after surgery (ERAS) is a multi-professional evidence based concept to ensure patients receive optimal

treatment and care (Kehlet and Wilmore, 2005). The genesis of the ERAS-programs are based on the question “why is the patient still in the hospital today?” given the following answer would clearly address the patients individually recovery problems (Kehlet, 2015). ERAS has successfully reduced length of hospital stay (LOS) across surgical specialities and suggests, that the concept should be expanded regarding its relative role in both pre- and postoperative adjuvant therapies in major cancer surgery (Kehlet, 2015, Cerantola et al., 2013).

Prehabilitation has been defined as the process of enhancing or maintaining an individual's functional capacity before scheduled surgery, aiming to improve the patient's tolerance to upcoming physiological stress (Gillis et al., 2014). The aspect of optimising the patient before surgery raises the dilemma prehabilitation versus

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rehabilitation. Based on the aforementioned aspects the question is whether adding a preoperative patient-education program in stoma care is an effective way forward to further optimise patient outcomes. Historically, the focus within stoma care literature has been on the experiences of the affected individual (O'Connor, 2005, O'Connor, 2003). Urostomy care requires manual skills and emotional adaption in order to secure self-efficacy (Kristensen et al., 2013) and there is mounting evidence that stoma care ability is the most important variable predicting positive adjustment to life with a stoma and increase the perception of Quality of life (QoL) (O'Connor, 2005, Danielsen et al., 2015, Vujnovich, 2008, Metcalf, 1999). A daily postoperative education-program in stoma self-care is a well known intervention and occurs during the patient's recovery in hospital after surgery (Metcalf, 1999, Vujnovich, 2008, Konya et al., 2006). However, follow up remains limited and significant unmet needs are described by survivors such as lack of early stoma-education and patient-involvement (Mohamed et al., 2014). Moreover, the literature reports that approximately only 50% of the patients adheres to stoma self-care two years post RC with a subsequent creation of an ileal conduit (Tal et al., 2012).

Providing the patient with adequate information and education before surgery is paramount and preoperative patient involvement is warranted in the RC-pathway (Mohamed et al., 2014). The positive impact of pre-operative stoma marking on clinical and patient reported outcome (PRO) has been reported (Salvadarena et al., 2015, McKenna et al., 2016). Thus, it has been hypothesized that adding preoperative stoma care education may be effective and improve self-efficacy as defined by Bandura (1977). So far preoperative stoma education has been discussed as consensus for good clinical practice in small descriptive studies and reviews based on expert knowledge (Kozell et al., 2014, Danielsen and Rosenberg, 2014), but the efficacy on preoperative stoma self-care skills has not been documented in a randomized design. In a prospective randomized controlled trial (RCT) the aim of this study was to investigate the efficacy of preoperative stoma-education on stoma self-care skills in patients undergoing RC with a subsequent creation of an ileal conduit because of bladder cancer.

1.1. Hypothesis

Preoperative stoma education improves stoma self-care following RC.

2. Methods

2.1. Participants

A parent prospective RCT investigated the efficacy of a multi-disciplinary rehabilitation program on LOS following RC (Registered in ClinicalTrials.gov Database NCT01329107). A total of 107 patients were included in the intention-to-treat population distributed by 50 patients in the intervention group and 57 patients in the standard group. The process of recruiting and randomization has been earlier reported (Jensen et al., 2015). The intervention group was instructed pre-operatively to a standardized pre-rehabilitation program consisting of both physical training and stoma-education. The content of the standardized physical pre-rehabilitation program and the results of physical training are reported elsewhere (Jensen et al., 2016).

Each patient was stoma sited according to international guidelines (Geng et al., 2009, Kozell et al., 2014). Five weeks post-surgery (day 35 post-surgery), all patients had a visit in the urostomy out-patient clinic, as standard of care, by two Urological Enteral Stoma Therapy Nurses (ET). A full change of appliance was performed and the patient was individually guided in case of lack of capacities in

any of the defined stoma self-care skills according to the Urostomy Education Scale (UES) (Kristensen et al., 2013). All patients included in this RCT-study were furthermore followed up by the project nurse regarding status of stoma self-care and other aspects related to the RCT-study at four and twelve months post-surgery (day 120 and day 365 post-surgery).

2.2. Intervention

The two ET's introduced and instructed the intervention group to basic stoma care and change of appliance using a training kit with an artificial stoma. The education program included basic skills to optimize the ability to perform independently stoma care. The patient was encouraged and recommended to perform stoma care and change of appliance, both one-piece and two-piece system, at least twice at home providing them with training kits and appliances. The patient was informed about the urostomy and life with a urostomy related to the individual patient's life and life style. Every patient had a follow up prior to surgery where the ET observed self-care skills regarding stoma care and change of appliance.

The standard group did not receive any of the aforementioned instructions or information prior to surgery.

2.3. Measurements

Progress in stoma self-care skills was measured using the validated UES; a standardized, validated and evidence based tool to document patients' level of stoma self-care skills (Kristensen et al., 2013, Kristensen and Jensen, 2016). The instrument was developed in collaboration with representatives from the European Association of Urology Nurses and yet a standard tool recommended by the American College of Surgeons. The UES is validated concerning face, content and construct validity. Moreover, UES is tested for reliability and found to be highly reliable among urology nurses with different level of experience in stoma care (Kristensen and Jensen, 2016, Kristensen et al., 2013). The scale is a quantitative scale aiming to determine individual urostomy self-care skills at any timeslot among patients undergoing RC. Areas recognized as standard procedure in urostomy care were identified and yet categorized into 7 skills necessary for changing a urostomy appliance (Fig. 1). The seven skills are; reaction to the stoma, removing the stoma appliance, measuring the stoma diameter, adjusting the size of the urostomy diameter in a new stoma appliance, skin care, fitting a new stoma appliance, and emptying procedure. Each skill is rated on a 4-point scale; possible scores range from 0 to 3 points. A score of 0 describes a patient being totally dependent on the nurse. A score of 1 describes a patient participating in the skill but needs assistance from the nurse. A score of 2 points describes a patient requiring verbal guidance from the nurse to complete the skill. A score of 3 points describes a patient who can complete the skill independently of the nurse. Possible cumulative scores vary from 0 to 21 points; higher scores indicate greater self-care skill acquisition.

2.4. Statistics

Differences in background data was tested by Students T-test for continuously variables, Pearson's Two-sided Chi-square Test for dichotomous variables and Ranksum Test for categorical. Efficacy was defined as a mean significant improvement in stoma self-efficacy between treatment groups and tested using the Student's T-test. The analyses were performed using an-intention-to treat approach (Schulz et al., 2010). Data was presented using a mean value including 95% Confidence Interval (CI). All statistical analyses

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