Official Title: Video Assisted Ablation of Pilonidal Sinus Versus Convention Off-midline Bas Com Cleft Lift Procedure

Brief Title: Video Assisted Ablation of Pilonidal Sinus Versus Conventional Treatment

Sponsor: Federico II University
Responsible Party: Principal Investigator
Investigator: Francesco Milone [fmilone]
Official Title: Professor of Surgery
Affiliation: Federico II University

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Study description: Video assisted ablation of pilonidal sinus (VAAPS) is a new endoscopic minimally invasive treatment. In an attempt to validate the effectiveness of the VAAPS, the investigators have designed a comparative study between the conventional and the minimally invasive treatment. Two surgical procedures were evaluated: VAAPS (Experimental group) and conventional excision with a Bascom out-midline closure (Control group).

Study design: An interventional randomized clinical trial. Patients were assigned to either the experimental or control group, using a computer-based randomization with sealed envelopes after informed consent has been obtained in the outpatient clinic.

Eligibility: The patients were included in the study if chronic non-recurrent sacrococcygeal pilonidal sinus was identified by an outpatient clinical evaluation. Exclusion criteria were inability to consent to the study, acute pilonidal disease (presence of abscess), recurrent disease and the presence of any co-morbidity.
Arms and Interventions: Experimental group include patients undergoing Video Assisted Ablation of Pilonidal Sinus. Control group include patients undergoing conventional off-midline Bascom cleft lift procedure.

*Video Assisted Ablation of Pilonidal Sinus* is a new 5-phases' technique. The 1st phase is to insert the endoscope through the external opening (orifice). In the patients that had more than one opening the lower pit is used for access. The 2nd phase is to identify the sinus cavity and its lateral tracks. The endoscope is advanced along the pathway using slow movements, left/right and up/down. These manoeuvres and the saline solution, used as distension medium, allow the sinus cavity to accommodate the endoscope. Additionally mechanical adhesiolysis with the forceps grasping could be useful. The 3rd phase is to identify the presence of hair and its removal. The 4th phase phase is to obtain complete ablation of sinus cavity. The sinus cavity and its lateral tracks are destroyed with the electrode under continuous direct vision. The 5th phase is to obtain the accurate cleaning of sinus cavity. The saline solution flow allows the elimination of any necrotic material. A Volkmann spoon could be useful to complete the cleaning.

*The Bascom cleft lift procedure* is a well describe procedure for the treatment of pilonidal sinus. The buttocks were pushed together, and the outer line of contact was marked. Beginning at 2 cm lateral of the midline, an incision was made 1–2 mm on the side of the sinus opening and curving around the anus. The skin from one side of the natal cleft was then elevated and excised. The skin on the opposite side of the cleft was undermined to a distance required to allow primary closure of the defect away from the midline without tension. The abscess cavity was curetted or scrubbed with gauze. The fat tissue of the natal cleft was approximated using absorbable (2/0 polyglactin) sutures. The wound was closed with 3-0 polypropylene interrupted mattress suture.

Outcome Measure: Wound infection (defined as redness and/or oedema of the skin and/or discharge), Recurrence (defined when symptoms of the disease recurred after an interval following complete wound healing), Return at work (Criteria for allow return to work was the absence of any limitation to normal daily activities, including no pain at rest and on movement, walking and sitting without pain and the lack of need to dress the wound more than once a day), Pain (A vas-score scale from 0 to 10) Satisfaction (a Vas-score scale from 0 to 10 and a SF_36 model will be used).

Statistical Analysis: Statistical analysis was performed with SPSS 16.0. The Yates corrected χ² test was used to evaluate differences in the categorical variables, and the independent sample t test was used to analyze continuous variables. Statistical significance was accepted when the P value was less than 0.05.