A Methodological Study To Formulate Ileostomy Moisture Associated Skin Damage Assessment Tool : A Multicenter, Cross – Sectional Study

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ABSTRACT: Stoma though saves life but it itself causes lot of problems and the most dreaded one is peristomal skin excoriation. Excoriated skin is defined as that which has been traumatized, worn away, or abraded, often in the presence of maceration due to incontinence. Cost of care was increasing day by day, unless this excoriation will treated. Most important and initial strategy in management of any disease was a thorough assessment. Lack of assessment is one of the major riddle in management of any disease. Currently there was no assessment tool for assessment of skin excoriation from ileostomy. No any proper guidelines or protocols are available yet at worldwide for assessment of ileostomy MASD except one SOP for ostomy care. Present study was aims to developed an assessment tool for "Ileostomy Moisture Associated Skin Damage". Study was Multicentre and participant from India and Indonesia (N=125) were enrolled. All participants have a well established knowledge of ileostomy skin damage as all of participants had work with ileostomy patients. More than the half of participants were graduates (68) and postgraduates (17). 117 participants were enterostomal therapist and remaining 08 participants were company personnel. Different types of ileostomy excoriation photographs were send to study participant and then asked to give stages of ileostomy skin excoriation along with suggestions. Among the 125 participants of the study who are mostly ostomy care nurses, registered a renowned figure of 100% of agreement with the study which means no sample was refused to be a participant.

KEYWORDS: Moisture Associated Skin Damage (MASD), Ileostomy MASD, Ileostomy Excoriation Tool, Ileostomy Excoriation Staging, Ostomy Care, Ileostomy Care, Enterostomal Therapist, Ostomy Care Nurse.

INTRODUCTION

Ostomy formation continues to have an important role in the treatment of colorectal and bladder cancer, constipation, pelvic floor dysfunction, and inflammatory bowel disease.[1] In principle, a stoma is an artificial opening through which the bowel protrudes, and is attached to the skin surface, allowing stool or urine to be diverted to the outside of the body.[2] The effluent must be separated from the skin, and contained within a pouching system that adheres to the skin.[3] Keeping this system working well and healthy is critical in maintaining a good, well-functioning stoma.[4] Keeping the peristomal skin intact proves to be a challenge for the patients, their caregivers, and the health care teams that work with them.[5] Ileostomies can prevent morbidity in septicemic patients of ileal perforation due to typhoid fever, tuberculosis, trauma, or ruptured appendix; however, complications (e.g., stomal obstruction, skin excoriation, dehydration due to high ileostomy output causing fluid and electrolyte loss) can occur in up to 16.9% of cases within 60 days.[6] Peristomal skin complications are shown to affect 18%–73% of patients.[7] Ileostomies, and in particular loop ileostomies, are responsible for the greatest proportion of peristomal skin complications.[8] Complications range from mild irritation to full thickness ulcerations leading to pain, anxiety, and in some cases significant social isolation related to the pouching system leaks. They are some of the most common postoperative complications, and usually occur within the first two weeks of the creation of the stoma. Peristomal skin complications can also present as late complications, months or even years after the initial surgery.[9] Treatment should be tailored to the underlying cause of the complication; it is critical that the underlying cause is diagnosed, so an appropriate treatment regimen can be instituted. Treatments range from simply using different pouching systems, to a change in local care regimen, to administering systemic medications if the cause of the complications is related to a systemic disease process, and in some cases surgery may be necessary.[10] Peri-stomal excoriation can be broadly defined as any wound that is adjacent to a stoma, including erosion or ulceration of the peri-stomal skin. It is most dangerous in iliostomy patients.[11]

Skin excoriation and ulceration are common and occur when the skin is exposed to ileostomy contents. This causes enzymatic digestion of skin proteins, damaging the skin. An international study of 279 ileostomy patients reported an overall complication rate of 83%, similar to our 72.6% rate. Both this study and the international study reported skin-related complications as most common: 19.4% of our study participants had skin excoriation, and 47% of patients in the international study had peristomal dermatitis.[12]

Better tools and enhanced techniques are fundamental building blocks in redesigning the clinical effectiveness paradigm, and new methods and strategies for evidence development are needed to use these tools to capture and analyze the increasingly complex information and data generated. Inflammatory or infectious conditions affecting the skin around an intestinal stoma are common and may be a source of considerable aggravation to patients. Recognition and prompt appropriate treatment of these conditions improves their quality of life.[13] Management of these all skin problems were started with assessment of ileostomy excoriation. Methodological research approach is most widely used research design to developed a new tool. In current worldwide scenario,

there are lack of measuring tool for ileostomy excoriation.Our author validated by sending an online assessment tool to enterostomal therapists from all government hospitals, autonomous body hospitals, corporate hospitals, trust hospitals, government medical colleges and private medical colleges in India. Our research team sent tool to ostomy care nursing company personnels who is working in long time 10yrs to more for validation of assessment tool. Wocare center is one of the prestigious and excellence of wound ostomy and continence care in Indonesia. We sent study for expert opinion and validate in Indonesia also. Our main author finally described a Ileostomy Moisture Associated Skin Damage Assessment Tool. Present study used to formulate a new tool to assess ileostomy excoriation.

Burden due to Ileostomy excoriation

It is estimated that the global market of stoma and ostomy care products was approximately USD3 billion in 2020 and US market has a figure of USD 886.9 million in 2021[14]. Despite having state- of -the art developments in the field of restorative colorectal surgeries, the number of patients having permanent stoma has substantially increased[14]. In my clinical practice, in an Indian top most tertiary care center, I've encountered on a daily basis that many doctors and nurses who are working in surgery, urinary, pediatrics and gastro surgery department also seemed to have little education to manage ostomy care. These Less trained staff while confronted with an ostomy patient, they fail to assess their client for any complications or exactly what care they are needed. This lack of education and knowledge can effect on ostomy management.[15-16] This Ileostomy Moisture associated skin damage (Table:- 1) covered staging of moisture associated skin damage surrounding ileostomy. In this article, the description,development purpose and the characteristics of Ileostomy Moisture associated skin damage (Table:-1) has created for those who having moisture associated skin damage surrounding ileostomy.

BURDEN DUE TO MOISTURE ASSOCIATED SKIN DAMAGE (MASD)

A study shows that ,in the USA,the number of patients having a stoma is more or less 750000 and about 130000 people among them used to go for a new ostomy every year.[17] There are many ostomy complication but moisture associated skin damage is more common.[18] Indeed maintenance of the peristomal skin is far more challenging to both caregivers and the patients asthere are a lot of pertinent moisture associated skin damage (MASD) . The severity of the complications can ranges from a mild erythema to the skin excoriation. The etiology is always complex as there are numerous contributing factors behind the issue. That can be sustained exposure of the surrounding skin to the moisture resulting from the effluent of stoma contents, mechanical injuries from adhesives used, bacterial or fungal infections, pressureinjuries, hypersensitivity reactions to the products used and sometimes auto immune response like pyoderma gangrenosum. Incidence rate of MASD after an ostomy has reported as 10 -70 percentage.[19] It is ironic that MASD can be prevented to a great extent as some studies have proved that availability of well trained nursing officers, active participation from client's side and early diagnosis and treatment had led to minimize the complications abundantly.[20-22]

Moisture Associated Skin Damage (MASD) around ileostomy

Moisture associated skin damage surrounding ileostomy is most common skin complication[23]. It can lead to redness, burning sensation or warmer, itching, pain and bleeding. Pancreatic enzymes are found inside ilum. Through ileostomy, faecal contents of the ilum come out, then due to excessive cutting of base plate of ostomy bag, the faecal contents remains on the peri ileostomy skin. The faecal contents begins Moisture associated skin damage(MASD) surrounding the ileostomy[24]. Moisture associated skin damage(MASD) is often result of faecal contents coming into contact with surrounding the ileostomy. Additional associated factor lead to chemotherapy, radiation therapy, adverse reaction or ostomy product allergy etc. A flush or retracted ileostomy (below the abdominal wall) can lead to faecal contents leakage between abdomen skin and ostomy base plate gets Moisture associated skin damage (MASD). Another most common reason for ileostomy contents irritation is an ostomy baseplate with an opening that is too large. Too much skin becomes exposed and faecal contents comes in contact with it, causing MASD surroundings ileostomy.

MASD has been introduced to damage that occurs in response to the prolong exposure of surrounding the ileostomy skin to ilum contents[25].

Table-1 : Participant data for Ileostomy Moisture Associated Skin Damage Assessment Tool

If you agree to contribute to the study kindly agree and provide answers to the following questions in the questionnaires.	
Agree	125
Disagree	0
AGE (YEARS)	
18-29	43
29-39	70
39-50	10
50-60	2
Gender	
Male	40
Female	85
Educational Qualifications	
Diploma	38
Graduate	68
Post graduate	17
Doctorate	2
In which area do you work.	
Autonomous body hospital	4
Central Government Hospital	10
State Government hospital	8
Private Hospital	97

Private Hospital	97
Wound and ostomy clinic	5
Are you Enterostomal therapist (ostomy care nurse)	
Yes	117
No	0
Company personnels	8
Are you doing ostomy care.?	
Yes	125
No	0
Total working experiences in clinical Field as a Enterostomal therapist or ostomy care nurse or ostomy care unit (in years)	
1-4	22
5-7	26
8-10	47
More than 10	30
Are you have knowledge regarding ostomy care	
Yes	125
NO	0
Are you agree for ileostomy excoriation stage -1st	
YES	118
NO	7
SUGGESTION	7
Are you agree for ileostomy excoriation stage -2nd	
YES	116
NO	9
SUGGESTION	9
Are you agree for ileostomy excoriation stage -3rd	
YES	121
NO	4
SUGGESTION	4
Are you agree for ileostomy excoriation stage -4th	
YES	98
NO	27
SUGGESTION	27

DATA COLLECTION

The clinical data related to Ileostomy Moisture associated skin damage tool in each center were collected. The questionnaire included 13 questions that formulate Ileostomy Moisture associated skin damage staging (Table-2). Simultaneously, an online survey was conducted for validate assessment tool and gather information about the ileostomy MASD staging from Enterostomal Therapist from India and Indonesia who had been working with ostomy care. A total of 132 questionnaires (Table-1) were collected. of which 125 were valid, but 7 of these were excluded because the respondents did not work in Ostomy care nurse (Table-1).

STUDY DESIGN AND PARTICIPANT

During the study period, all Enterostomal Therapist and company personnels were actively involved in the care of ostomy care patients. Ostomy care included nurses and company personnels who has dedicated working for ostomy care. The study questionnaire, written in English and asked about general demographic, attitude, working area, clinical experience in clinical field. (Table-1)

STATISTICAL ANALYSIS

The aim of this study is to formulate Ileostomy Moisture associated skin damage staging first to fourth in ostomy care. Improper pouching system, retracted stoma and wrong cutting ostomy base plate gets MASD surrounding Ileostomy. We formulate four staging (Table-2) and sent to all enterostomal therapist of India and WOCARE Centre, Indonesia. Our purpose is Validate tool, review and suggestion regarding Staging from Enterostomal Therapist of Super speciality hospital. We gets clinical review and suggestion and then againg modified Ileostomy Moisture associated skin damage staging(Table-2). We gets suggestion 7 out of 125 in Ileostomy Moisture associated skin damage stage-1st (Table-1) and then modify and present againg stage-1st (Table-2nd). We gets suggestion 9 out of 125 in Ileostomy Moisture associated skin damage stage-2nd (Table-2) and then modify and present againg stage-2nd (Table-2nd). We gets suggestion 4 out of 125 in Ileostomy Moisture associated skin damage stage-3rd (Table-2) and then modify and present againg stage-3rd (Table-2nd).

We gets suggestion 27 out of 125 in Ileostomy Moisture associated skin damage stage-4th (Table-2) and then modify and present againg stage-4th (Table-2nd).There were, therefore, informal hypotheses being implemented to drive the sample size calculation and we included the maximum number of review and suggestion regarding Ileostomy Moisture associated skin damage staging and then finally prepared Ileostomy Moisture associated skin damage Staging for globally use.

Table – 2nd : Ileostomy Moisture Associated Skin Damage Assessment Tool (IMASDAT)	
Stage	Skin Changes
1st	Intact skin with non-blanchable redness of surrounding ileostomy area. Darkly complexion person have skin may not have visible blanching; its color may differ from the surrounding ileostomy area.minor red ness surrounding the stoma, patient feel burning surrounding the stoma. The area may be burning sensation and warmer. Staging-1 may be difficult to detect excoriation in individuals with dark skin tones. May indicate “at risk” persons.
2nd	Loss of epidermis surrounding the ileostomy presenting as shiny a red-pink dermis. Excoriation with sero-sanguineous fluid and without blood. May also present as an intact dermis. Presents as a shiny dermis colour. This stage should be used to describe ileostomy excoriation.
3rd	Loss of dermis, hyperaemic peri ileostomy area, Excoriation with sero-sanguineous fluid and blood, Subcutaneous fat may be visible, but bone, muscle is not exposed. Slough may be present, but does not obscure the depth of tissue loss.
4th	Loss of subcutaneous tissue and excoriation extend to muscles, along with mucutaneous separation, necrotic slough surrounding ileostomy, granuloma, deep folds, retracted stoma, stiches, Stomal and peri stomal hernia, Stoma prolapse, Stomal bleeding, Peristomal folliculitis, Stomal cancer.

DISCUSSION AND RESULTS

Among the 125 participants of the study who are mostly ostomy care nurses from India and WoCare, Centre Indonesia(Table-1). Registered a renowned figure of 100% of agreement with the study which means no sample was refused to be a participant (Table-1). Indians were the majority among the participants with far better of 120, whereas, the other nations had comparatively less participation as 5 from Indonesia. As many ostomy care nurses of the samples were belong to highly specialized and younger age group. More than the half of participants were graduates with 68 and postgraduates who indulged in study also had a better figure of 17. Only a nominal of 2 members were completed their PhD showing (Table-1). Among all, the lion's part of study was bagged by Female with an astounding of 85 while males contributed very diminutive figure of 40(Table-1). Among the participants, an exact half of them were belong to the age group of 29-39yrs with 70 and about 43 were between 18-29yrs,10 were in 40-50yrs and a meagre of 2 were belong to the 50-60yrs age group (Table-1). The survey had depicted that majority of health care workers who have been working in private sector and very less in government sector were participated in the study. It is well known fact that with times went by as more experience and skilled Ostomy care nurses achieve they indeed can deliver high quality care than less experienced one. Also some studies have shown that most of the Enterostomal therapist who worked to management of ileostomy excoriation comparatively less very reliable and completely reviewed Ileostomy MASD Staging in globally. Evidences suggests that there is an inverse relationship between the number of years that ostomy care nurses has been in Super specialized medical college and research centre and the quality of care they deliver. In this study majority of the respondents were more experienced in ostomy care field. Ostomy care nurses are showing high level of compliance that how to assess the ileostomy MASD. This survey aim to analyze what all things have been learned by the ostomy care nurses about management of ileostomy excoriation and how to improve the assessment in ostomy care unit of hospital. This study was focused to formulate a fully reliable ileostomy MASD tool for globally (Table-2). It has been noted that detailed standard operating procedure for management of ostomy care [26]. However, any special suggestions haven't seen yet about how to assess the ileostomy excoriation caused by MASD. We found that ostomy care professionals doing appreciably good quality care to ostomy patients by own knowledge. But there is too much neglected evidence based practice in ostomy care. No any proper guidelines or protocols are available yet at worldwide for assessment of ileostomy MASD except one SOP for ostomy care.[26] It has been noted that no appropriate assessment tool for ileostomy MASD in globally. Here author aim is to how to assess the ileostomy MASD and every ostomy care nurse of super speciality medical college do ostomy care on the behalf of Proper SOP for ostomy care.

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