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Article

Clinical research on stoma patients: validation of TOR Form for evaluation and monitoring

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Abstract. *Background:* The absence of exact data for stoma patients, and the low attention given to results obtained through current protocols, lead to the study of a dedicated research form. *The Toma Ostomy Research Form* (TOR Form) was created following the need to have a standardised and validated form to gather data, to be used in the clinical and observational research on stoma (urinary and/or intestinal) patients.

Method: The TOR Form for monitoring osthomates for a time of 28days, is devised in a section for initial assessment, and separate sections for each following evaluation and for follow up. To enable the form validation, the same patient was assessed by two different nurses evaluators, during the same treatment/dressing change session. After having agreed on the wound/issue to be assessed, the two assessments were carried out at 10 minutes' distance one from the other. 45adult patients, stoma carriers (intestinal and urinary), following the same treatment protocol were enrolled as sample.

Results: In the general patient's assessment, normally the suitability for using validated scales (Barthel Index, Braden, MNA, NRS, PAINAD) is quite high ($p<0.001$). If used correctly, they do not allow margins for error. As regards the stoma assessment, the Cohen's kappa coefficients has values around 0.784-1($p<0.001$), except for two items (peristomal skin and new peristomal wound)

in which the value, overall acceptable, is 0.656($p<0.001$). This demonstrates that the description factors used are adequate for the various situations observed.
Conclusions: The results obtained confirm that the TOR Form is a valid tool for clinical and personal data collection. The form can be used as a data collection for clinical research purposes, as well as nursing documentation in monitoring the stoma-carrying patient.

Keywords: ostomy research, stoma complications, ostomy care, stoma evaluation, ostomy assessment.

Introduction

Inflammatory and oncology conditions are increasingly frequent causes leading to intestinal or urinary stoma[1].
An abdominal ostomy necessarily involves an adequate therapeutic training of the patient and/or his care giver to manage daily hygiene and the ostomy pouching system[2]. Contact of stoma output with peristomal skin often lead to skin lesions[3-9], which, besides creating issues with adhesiveness of the stoma applied, have a negative effect on patients' quality of life[5].
There is no precise evidence on the number of patients with peristomal lesions (PL), but it is estimated that the percentage of this patients could range between 20-70%[3,5].
Unfortunately, the experience grown in the wound care area[10,11] is often neglected when treating PLs, and advanced technologies[12]/wound dressings are rarely used. Standard treatments involve the use of traditional dressings, without specific protocols.
The absence of exact data, and the low attention given to results obtained through current protocols, lead to the study of a dedicated research form[13-22].

The TOR Form (Toma Ostomy Research Form) was created following the need to have a standardised and validated form to gather data, to be used in the clinical and observational research on stoma (urinary and/or intestinal) patients. This need arose from the absence in literature of validated tools such as this.
It has been used to collect clinical data and to monitor stoma patients in a few case studies[23,24], and it had proven to be a complete and versatile tool, appreciated by clinical specialists (**Attached 1 and 2** – TOR Form in English and Italian version). The aim of this study is therefore to carry out a validation of the form for the monitoring of stoma patients.

METHODS

Description of the form

The TOR Form is devised for global monitoring stoma patients, and the stoma and peristomal skin evolution, for a time of 28 days. There is a section on the initial assessment – Time 0 (T0), and separate sections for each following evaluation and for follow up.

Check intervals are defined at:
Time 1 (T1)- 7 days
Time 2 (T2)- 14 days
Time 3 (T3)- 28 days
Time 4 (T4) - follow-up (to be decided according to objectives and treatment applied).
The form is therefore divided in six sections: one for initial assessment (T0), four for assessments at the pre-established set times (T1, T2, T3, T4) and the last one for the lesions' evolution during in-between dressing changes/treatments.
For all the period of research, attention is not only focused on the clinical outcome, but also on the patient's expressed compliance.

Patient's initial assessment

During the initial assessment, there is the general assessment of the patient, of the stoma, of the surrounding skin, and of any peristomal wound present. There is a space for describing the previously used peristomal hygiene protocol and the one followed during the observation period, seen its importance to maintain skin integrity[2].
There is also a space to describe the evaluation's protocol/treatment.
Every patient on enrolment was given an enrolment code which would ensure his/her anonymity. The evaluator's identity was also registered; this is important in case of data discrepancies, to understand if it is due to the clinician or to the clinical result obtained.

The initial section has 7 items for information on: gender, age, weight, height, concurrent conditions, type of ostomy, time passed since the stoma procedure, type of ostomy pouching system used.
To respect privacy and anonymity of the patient, there is no space for indication of geographical belonging. This information could be collected if the researcher decides it is important for the research in the light of the chosen objectives (e.g.: if the clinical outcome to treatment of patients belonging to two distinct geographical areas is to be compared, this information becomes indispensable).
In the field of pathologies present we chose to register specifically the presence of neoplasias (with treatments of chemo- and radiotherapies), Crohn's disease and diabetes, since they can all influence the patient's general condition, the specific state of the ostomy, and the healing of peristomal wounds.

Besides the personal data, in order to reduce the potential mistakes in collecting the patient's general information by the clinician, we decided to adopt well known and validated evaluation scales, as follows:
- The self-sufficiency evaluation of the patient was assessed using the *Barthel Index*, specifically the version adapted to Italian language and culture (for research carried out in Italy), validated in 2015[10,25]. In the fields for the management of the intestinal/urinary tract, in case of presence of corresponding stoma, the patient able to manage autonomously the pouching system and the stoma was considered "*able to control the transit*".
- The evaluation of risk of developing pressure ulcers, to be carried out on all patients with a *Barthel Index* < 100, was measured with the aid of the *Braden Scale*[26,27].

- The evaluation of the patient's nutritional state and malnutrition risk was carried out using the *Mini Nutritional Assessment Scale* (MNA)[10,28].
- The pain evaluation, compulsory in Italy according to Law 38/2010 – "*Rules to guarantee access to palliative treatment and pain therapy*"[29], was carried out **on all enrolled patients**. Intensity of pain related to stoma was assessed using the *Numerical Rating Scale* (NRS)[10] for able-minded patients and the *Pain Assessment in Advanced Dementia* (PAINAD)[10,30,31] for patients with cognitive impairment.
- The assessment/classification of peristomal wounds was carried out using the *SACS Scale 2.0*[32], variation of *SACS Scale*[33] updated in 2016.

Also the value of urinary pH has been taken into consideration. It was noted only for patients with urinary stoma, if there were lab urine tests done within 15 days from the evaluation.
Besides the patient's general condition and the classification of the peristomal wound skin observed, there is a field for assessing the condition of the stoma, the surrounding skin and the presence of any other complications.

In the field Research Protocol, we included the protocol, object of the study, used for the full observation period.
At the end of the form there is a specific field for monitoring the peristomal wounds during dressing changes/treatments carried out in dates different from the ones defined for standard evaluations. In these occasions, it was only noted if the state has worsened, staid the same, improved or healed.

Subsequent assessments

In the sessions for subsequent assessments (T1, T2, T3, T4), body weight and self-sufficiency state were always registered, since these data could change in time and affect the evolution of the patient's state.
There is a field for registering new wounds, different from the wounds noted in the initial assessment. The new wounds were always assessed using SACS Scale 2.0. It is important that all the staff of clinicians participating in the research is informed and agrees on the starting wound observed, to avoid confusing the appearance of a new wound with a worsening of an existing one.

Application

The data obtained through a systematic collection using the TOR Form can contribute to an increase of quality of care[34-36], since the user is lead to use validated scales[37]; this also decreases work-related stress[38], and implicitly also results in a decrease of healthcare expenditure.
The TOR Form can be used to collect data in clinical research on treatment application and protocols for:

- presence of peristomal skin alterations/wounds,
- stoma problems, such as mucocutaneous separation, granulomatosis, oedema, bleeding, etc.),
- protocols and/or products of comparison.

It can also be used for evaluating and monitoring:

- application of ostomy pouching system (single or in comparison),
- application of stoma management protocols (such as the peristomal skin hygiene protocol, treatment peristomal wound).

In order to proceed with the validation of the form, we decided to have the same patient assessed by two different evaluators, both nurses, during the same treatment/dressing change session. After having agreed on the wound/issue to be assessed, the two assessments were carried out at 10 minutes' distance one from the other. The evaluators could not meet.

A sample of 45 adult patients, stoma carriers (intestinal and urinary), all following the same treatment protocol were enrolled, in a period of 3 months (December 2018-February 2019). Previously to enrolment, they all gave their consent to participate in the study.

The panel of participating evaluators was composed by clinical specialist nurses with a post-basic university specialisation (I Level Master in Stoma Care and/or I Level Master in Wound Care). All had a good knowledge of the scales used and were familiar with the TOR Form[23,24], having previously used it.

RESULTS

Sample composition

A sample of 45 adult patients, stoma carriers (33 intestinal stoma, 11 urinary stoma and 1 patient with both intestinal and urinary stoma), all following the same treatment protocol were enrolled. In **Table 1** the characteristics of the selected patients are presented.

The patients had a mean age of 68.6 years [range 28-90]; of which females 42.2%(19), males 57.8%(26); stoma present for less than 11 months 26.7%(12), between 1-5 years 28.9%(13), more than 5 years 44.4%(20). The composition of the sample as regards age and gender is comparable to the ones found in other studies on stoma patients[13,39,40] covering the period 2004-2016.

33 patients, equal to 73.3% had intestinal stoma, 11 (24.4%) urinary stoma and 1 (2.2%) had both types; main cause of stoma was neoplastic pathology in 55.6%(25) of cases.

As regards body weight, 46%(21) of the sample was of normal weight or underweight, and 53.3%(24) overweight/obese [BMI range 16.73 – 32.05kg/m^2; average BMI 25.1 kg/m^2]. Nutritional assessment through the MNA Scale showed normal state (MNA >24) in 46.7% (21) of the sample, and malnutrition risk was showed in 48.8% (22) (MNA <17 and 17 – 23.5), [range MNA 16-29].

From the point of view of self-sufficiency, evaluated through the *Barthel Index*, the majority of the sample, 51.1% (23), was partially self-sufficient and 29% (13) was totally self-sufficient [range Barthel Index 20-100].

The stoma pouching device used was a two-piece device in 66.7% (30) of the sample, and in 33.3% (15) a single-piece device.

Table 1. – Characteristics of the selected patients

Variable	Mean (SD) or N (%)
Age (range 28-90 years)	**68.6 (15.4)**
Gender	
Females	**19 (42.2)**
Males	**26 (57.8)**
BMI	**25.1 (3.8)**
Underweight: < 18.5 kg/m^2	**3 (6.7)**
Normal weight: 18.5 kg/m^2 – 24.9 kg/m^2	**18 (40.0)**
Overweight: 25,0 kg/m^2 - 29.9 kg/m^2	**21 (46.6)**
Obese: > 29.9 kg/m^2	**3 (6.7)**
Pathologies	
Diabetes	**5 (11.1)**
Crohn's Disease	**4 (8.9)**
Tumor	**25 (55.6)**
Tumor and diabetes	**5 (11.1)**
None of the above	**6 (13.3)**
Neoplasms affected ongoing : chemotherapy	**5 (11.1)**
Neoplasms affected ongoing : chemotherapy and radiotherapy	**1 (2.2)**
Ostomy bearer since	
< 2 months	**4 (8.9)**
3 -11 months	**8 (17.8)**
1 – 5 years	**13 (28.9)**
>5 years	**20 (44.4)**
Type of ostomy	
Intestinal stoma	**33 (73.3)**
Urinary stoma	**11 (24.4)**
Intestinal and urinary stoma	**1 (2.2)**
Ostomy appliance	
One-Piece	**15 (33.3)**
Two-Piece	**30 (66.7)**
Autonomy Status: Barthel Index	**68.22 (20.92)**
0 - 55 (no self-sufficient)	**9 (19.9)**
60 - 85 (partially self-sufficient)	**23 (51.1)**
90 – 100 (totally self-sufficient)	**13 (29.0)**
Risk assessment	
Pressure ulcers: BRADEN	
12 (Risk 12-16)	**4 (8.9)**
> 16 (Low risk)	**41 (91.1)**
Malnutrition: MNA	**22.67 (3,4)**
>24 (nutritional state: normal)	**21 (46.7)**
17 - 23,5 (malnutrition risk)	**22 (48.8)**
<17 (risk of malnutrition by defect)	**2 (4.4)**

Agreement between the observers

We analysed the agreement between the two evaluators who observed the same patient on: patient's global assessment (self-sufficiency, risk, pain, urinary pH), the stoma condition (appearance, colour, protrusion, mucocutaneous junction, complications), the peristomal skin assessment and the presence, classification, position and evolution of any skin lesions (**Table 2**).

Table 2. –Agreement between the two observers

Variable	Cohen's kappa (concordance correlation coefficients)	P (approximate significance)
Patient global assessment		
Autonomy Status: Barthel Index	1.000	<0.001
Pressure ulcers risk: Braden Scale	0.967	<0.001
Malnutrition risk: MNA	1.000	<0.001
Stoma-related pain: NRS (in a fully conscious and vigilant patient)	0.971	<0.001
Stoma-related pain: PAINAD (in a patient with cognitive impairment)	1.000	<0.001
pH Urine value (with urinary ostomy)	1.000	<0.001
Ostomy evaluation		
Stoma appearance (healthy, oedematous, granulomatous, lacerated)	1.000	<0.001
Stoma color (red, pasty, dark red, grey/black)	1.000	<0.001
Stoma protrusion (flush, at cutaneous level, normal, prolapsed)	1.000	<0.001
Mucocutaneous junction (intact/detached)	1.000	<0.001
Peristomal skin state (intact/ with lesions)	0.656	<0.001
Complications (retraction, prolapse, necrosis, hernia, mucocutaneous separation)	1.000	<0.001
Peristomal wound assessment and classification (using SACS 2.0)		
Classification of wounds present in T I	0.784	0.003
Classification of wounds present in T II	1.000	<0.001
Classification of wounds present in T III	0.843	0.002
Classification of wounds present in T IV	1.000	<0.001
Classification of wounds present in T V	1.000	<0.001
State of wound/s compared to the same at the start of treatment (healed, improved, unchanged, worsened)	0.961	<0.001
New peristomal wounds present (Yes/No)	0.656	<0.001
Peristomal hygiene		
Material previously used (paper, gauze, sponge, cellulose cloth, wet tissue, other)	1.000	<0.001
Previous hygiene (no soap/detergent, same soap used for body, other)	1.000	<0.001
Hygiene applied during monitoring stage (same, other)	1.000	<0.001
Hygiene compliance (positive/negative)	1.000	<0.001
Compliance with treatment used (positive/negative)	1.000	<0.001

In the general assessment of the patient the concordance correlation are generally very similar, close to 100%, ($p<0.001$), due to the use of validated scales (*Bartehel Index*, *Braden Scale*, MNA, NRS, PAINAD) which, when correctly applied, do not allow room for error. A slight dis-homogeneity can be observed as regards pain assessment (concordance correlation coefficients[40,41] *Cohen's kappa* 0.971; $p<0.001$). Since pain can really vary in an objective way even is short intervals of time, the value observed can be consistent with the intensity the patient actually felt.

As regards the nutritional assessment through the MNA, even though our research showed a good concordance correlation, care should be taken when the assessment is based on the patient's statements. A direct and precise observation of feeding habits can be carried out only when the patient is hospitalised.

Equally good is the concordance of the two evaluators when assessing the stoma ($p<0.001$), which proves that the descriptions used are comprehensive for the various situations found.
In the observation of the evolution of peristomal lesions there were different opinions, when the evaluators did not initially agree on which is the lesion to be monitored. Therefore, a discrepancy can be found, as a new lesion occurrence can be mistaken for the worsening of the original wound (Cohen's kappa-0.961; $p<0.001$), or a new wound appearing can be considered a recurrence of a previous lesion which had healed (Cohen's kappa -0.656; $p<0.001$). This could be easily avoided by better training of the evaluator on the use of the form and by setting the instruction to agree and share the information within the team, on which lesion is to be monitored, at the very onset of the patient enrolment.

DISCUSSION

The increase of inflammatory[42] and neoplastic pathologies which contribute to the increasing need of performing stomas, request a higher attention on the development of research and on the better quality of health care treatments provided.
The 45 patients enrolled for the study, average age 68.6 years, although mostly partially self-sufficient and with a stoma for more than 5 years, all had at least one problem either at stoma site or on peristomal skin (maceration, lesions). These problems required an assessment by the evaluators at enrolment time. In the vast majority of cases, the issues derived from an inadequate peristomal hygiene, or bad management of the collection devices, both due to an insufficient therapeutic education of the patients.

The number of patients enrolled was low due to the short time allowed for the project development and to the impossibility for some patients to be available for the pre-established check times; however, the sample resulted to be adequate to show a good agreement of the evaluators' assessments, and a good effectiveness of the tool.
The suggested short study timespan (3 months) did not allow us to specifically train in the use of the form clinical personnel without experience in management of stoma patients.

For the project of data collection, we chose a panel of clinical specialist nurses with post- basic university specialisation (I Level Master in Stoma Care and/or I Level Master in Wound Care), with good training and knowledge of the evaluation scales included in the form. The experience

and good training of the evaluators has been an added value in identifying and correcting any mistakes, and enabled us to achieve in a very short time the final format of the form. The use of TOR Form for any project involving research and/or data collection, will require prior ascertaining that the personnel involved has adequate training, and that they have a good knowledge of the validated scales and of evidence based practice; alternatively, specific training to the use and way of compiling the TOR Form will be mandatory.

Although initially considered important in the research, data regarding marital status and education level of the patient were crossed out from the final form, as they were perceived by some patients as an invasion of their privacy and not directly linked to the pathology.

The enrolment of a patient presenting a double stoma (intestinal and urinary) made us realise that this category is not widely studied, and following our researching the relevant literature, we found that it is not included in any validation study. In the case of the use of TOR Form this category was included; however, when enrolling the patient, it is necessary to specify if both stoma present will be observed, or only a specific one.

In case the subject of the study should be peristomal lesions, it is important to remember to agree and note, on enrolment, which is the lesion initially to be assessed and monitored. In this way, if during the monitoring period the patient were to be seen by different evaluators, the confusion of a new lesion occurrence and the worsening of a previous one, or vice versa, can be avoided.

The fact that in our search we did not find in literature a validated similar evaluation tool, did not allow us to proceed with a qualitative and quantitative data comparison, but only a comparison of the characteristics of the sample enrolled versus other validation papers. Our sample, with an average age of 68.6 years [range 28-90], of which females 42.2%, males 57.8%, a percentage of urinary stoma of 24.4%, an average BMI of 25.1 kg/m^2 is comparable to other studies such as:

- Olbrisch ME (1983)[16]: 53 patients, males 54%, urinary stoma 20.7%;
- Indrebø et al. (2016)[42]: age range 29-91, females 44%, males 56%;
- Dellafiore et al. (2019)[43]: average age 71.62, average BMI 24.36 kg/m^2.

Conclusions

The use of a validated documentation can contribute to an increase of quality of care and to a decrease of nurses' stress[38] since it eliminates the worry on any possible mistakes on data collection due to lack of attention.

The start of a clinical research with a validated and standardised data collection form, complete as regards the patient's personal, anamnesis and clinical data, allows the comparison between studies, and facilitates any literature revision work.

TOR Form is a data collection form devised for clinical research, but it can also be used as a form/documentation system for nurses, in order to monitor stoma patients within a 28 day period; in this use, it can be included in the hospital or day clinic file.

Authors' contributions

ET participated in the creation of the form, design of the study, supervised the data collection and drafted the manuscript. GLT performed the statistical analysis, participated in the design of the study and to the manuscript's drafting. MSE, ADM, FB planned and collection the clinical data. All the authors read and approved the final manuscript.

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