

Evaluating the Effectiveness of a Novel Skin Barrier Protectant in a Patient with Acute Radiodermatitis of the Vulva: A Case Report

Peer-reviewed author version

Van Bever, Leen; Claes, Stefan; ROBIJNS, Jolien; Censabella, Sandrine; Pannekoeke, Luc; Van de Werf, Evelyn & BULENS, Paul (2021) Evaluating the Effectiveness of a Novel Skin Barrier Protectant in a Patient with Acute Radiodermatitis of the Vulva: A Case Report. In: Advances in skin & wound care, 34 (1) , p. 49 -55.

DOI: 10.1097/01.ASW.0000722768.95461.82

Handle: <http://hdl.handle.net/1942/33039>

## **Manuscript**

### **Title**

Evaluating the effectiveness of a novel skin barrier protectant in a patient with acute radiodermatitis of the vulva: a case report

### **Abstract**

#### **Objective**

To evaluate the use of Cavilon Advanced Skin Protectant in a patient treated with radiotherapy for vulvar cancer.

#### **Design**

Case report study

#### **Setting**

Radiotherapy department

#### **Participants**

Two female patients undergoing radiotherapy for vulvar carcinoma.

#### **Interventions**

In this case report study a novel skin barrier protectant, Cavilon Advanced Skin Protectant, was evaluated in a patient treated with vulvar radiodermatitis. Besides, another patient with vulvar radiodermatitis undergoing the institutional standard skin care protocol was portrayed.

#### **Main Outcome Measures**

Patient's skin reactions were evaluated by using the Radiotherapy Oncology Group Criteria by a radiotherapy nurse, alongside the patient's pain.

## **Main Results**

The patient that was treated with the skin protectant showed accelerated healing towards the end of radiotherapy and this was accompanied with a decrease in pain (<6/10). The patient treated with the standard skin care protocol, had an extended healing process, suffered from a lot more pain (>8/10), and required more nursing care.

## **Conclusions**

This case report is the first to suggest that Cavilon Advanced Skin Protectant could be used to effectively manage acute radiodermatitis in patients with cancer. This study laid the foundation for future randomized control trials with a larger and broader patient population.

## **Key words**

- Cavilon Advanced Skin Protectant
- Radiation dermatitis
- Radiotherapy
- Vulvar carcinoma
- Case report

## **Main text**

### **Introduction**

One of the most unavoidable side effects of radiotherapy (RT) is the development of acute skin reactions, also known as acute radiation dermatitis (ARD). Notwithstanding, the improvements in the RT techniques, it still occurs in up to 95% of the patients with cancer of different etiologies.<sup>1-3</sup>

The skin toxicity caused by ionizing radiation is a continuous process, which has a cumulative effect, resulting in more damage when RT progresses. RT causes an inflammatory reaction accompanied by vessel damage in the irradiated area leading to an erythematous skin reaction, which is clinically visible two weeks after the start of RT. In the meantime, the ionizing beams also damage the stem cells of the basal skin layer, leading to a disruption in the normal skin regeneration process. The skin will try to compensate for the loss of cells by stimulating the production of new stem cells. When the production of new cells is faster than the shedding of dead cells at the skin surface, dry desquamation arises. Towards the end of RT, the stem cells can become depleted, resulting in moist desquamation.<sup>4,5</sup> Overall, RT negatively affects the skin barrier function, which makes the skin more vulnerable for water loss, chemical elements, allergens, ultraviolet radiation, leading to increased risk of dehydration, infections, and sun burns.<sup>6,7</sup>

Clinically ARD can be graded based on the criteria of the Radiation Therapy Oncology Group (RTOG) (table 1).<sup>8</sup> The risk on ARD is depended on various treatment- and patient-related risk factors (e.g. RT regimen, RT dose, chemotherapy, smoking, skin folds, comorbidities, etc.).<sup>9-12</sup> Especially the skin of the vulva has a very poor tolerance to

RT due to its anatomical location, constant abrasion, and moisture. RT can also damage the epithelium of the small and large intestines and cause cystitis leading to the onset of diarrhea and frequent urination. The exposure of the skin in the perianal region to urine and stool increases the risk on irritation, infection, and bacterial contamination, which increases the risk on sepsis. The incidence of vaginal ARD is poorly documented, but available scientific evidence demonstrates that between 50 and 70 % of the patients develop grade 3 ARD in the vulvar region during the RT course. In addition, wound care practices are rather difficult in this anatomic region due to the presence of moisture, skin folds, and frequent defecation.<sup>13-19</sup>

Vulvar ARD impairs the patients' quality of life (QOL) and can be painful in the case of moist desquamation, which negatively influences the patients' daily life. Patients have to cope with washing, clothing, and hygiene problems, which can last for several weeks to months after their final RT session. In some severe cases of vulvar ARD, the radiotherapist can decide to interrupt RT based on the patient-related risk factors in order to prevent worsening of the skin reactions. This can reduce the success rate of the treatment and the patient overall survival.

Today, there still lacks a consensus on the prevention and management of ARD.<sup>2,3,20,21</sup> Though, the Multinational Association of Supportive Care in Cancer (MASCC) published guidelines for the prevention and treatment of acute and chronic RD. Based on these guidelines a strong recommendation was made for gentle washing the irradiated area with water, with or without mild soap and the use of topical steroids to reduce the risk on ARD.<sup>22</sup> Still, a lot of potential, beneficial preventive and therapeutic therapies are under

investigation. Many institutes develop their own protocol for the management of ARD based on clinical experience.<sup>23</sup>

Skin abrasion is an important risk factor for the development of ARD. Therefore, skin barrier products might offer a solution to this issue. A skin barrier product offers protection against abrasion by physically reducing the desquamation process of the skin, resulting in a prolongation of the life of the intact superficial skin cells. Additionally, a skin barrier product can protect intact or damaged skin from irritation caused by urine and/or fecal incontinence, digestive juices, wound drainage, adhesives, friction, and shear.<sup>24</sup>

To date only two clinical trials investigated the use of a skin barrier film in patients with breast cancer that underwent RT. They used the Cavilon No Sting Barrier Film which is an alcohol-free liquid barrier film that protects intact or damaged skin from bodily fluids, adhesive trauma, friction, and incontinence. However, this product cannot be applied on moist wounds.<sup>25</sup>

In a study by Graham et al., 61 patients with breast cancer treated with RT post-mastectomy applied Cavilon No Sting Barrier Film to either the medial or lateral half of their irradiated chest area. Results showed that the barrier film reduced the duration and frequency of radiation-induced moist desquamation.<sup>24</sup> Shaw et al. studied the same skin barrier film in 39 patients with breast cancer that underwent RT post-lumpectomy or mastectomy and demonstrated that the skin barrier film could reduce the incidence of pruritus.<sup>26</sup>

In this case report, a new formulation of a skin protectant, the Cavilon Advanced Skin Protectant <sup>27</sup>, was tested for the first time in one patient undergoing RT for vulvar carcinoma. This new skin protectant acts as a physical barrier against abrasion, moisture, and irritants. Moreover, it enables an environment for wound healing. The emerging aspect of the Cavilon Advanced Skin Protectant is the combination of a proprietary acrylic tetrapolymer with a 2-octyl cyanoacrylate. The cyanoacrylate makes it able to apply the skin protectant to dry, wet, and moist wounds. Whereas, the polymer ensures that it forms a long-lasting waterproof, highly durable film barrier, which is elastomeric and ensures durability, compared to pure cyanoacrylate solutions. Moreover, the film is transparent and moist- and air permeable. An *in vivo* study with a porcine partial-thickness wound model demonstrated that the skin protectant provides a barrier against irritants and favors healing of intact and damaged skin.<sup>28</sup> A clinical trial with incontinence-associated Dermatitis (IAD) patients showed that the use of the Cavilon Advanced Skin Protectant led to a significant reduction in IAD scores and IAD-associated pain.<sup>29</sup>

The purpose of this case report study is to describe and discuss for the first time the use of Cavilon Advanced Skin Protectant in comparison with the institutional standard skin care in two patients with vulvar ARD.

## **Methods**

A comparative case report study was performed with two patients with vulvar cancer that underwent RT at the Limburg Oncology Center (LOC), Jessa Hospital (Hasselt, Belgium) in the period 2016-2017. The case reporting guidelines (CARE) guidelines for the reporting of case studies were followed for the present study.<sup>30</sup> The patients provided a written informed consent for the processing of personal data and a waiver for the use of photographs. The study complied with the Helsinki Declaration guidelines on clinical research and with legislation on the protection of privacy.

## ***Interventions***

### *Radiotherapy*

Both patients were treated with rotational intensity modulated radiation therapy (IMRT) using photon beams. Patients were placed in a supine position with their legs spread supported with a knee fix. They received 35 daily fractions between 1.8 and 2 Gy, for a total dose between 65 and 70 Gy.

### *Institutional topical skin care treatment*

Each patient was individually advised to follow the institutional skincare guidelines, which were based on the local guidelines of the Flemish Association for Radiotherapy and Oncology Nurses (e.g. wear loose fit clothing, gentle washing with or without mild soap, patting dry with a soft towel instead of rubbing).<sup>31</sup> Further, the patients were instructed to apply daily the Cavilon No Sting Barrier Film (3M Health Care; Minnesota, USA) on intact irradiated skin in combination with the Cavilon Contenance Care Wipes (3M Health Care; Minnesota, USA) to clean the skin after each toilet visit. In case of vaginal irritation, a



Kamillosan sitz bath (>1x/day) was recommended. This was combined with Foam, absorbent, self-adhesive silicone dressings (Mepilex, Mölnlycke Health Care, Gothenburg, Sweden) were used in the case of painful skin reactions and to prevent friction from the patient's underwear.

#### *Cavilon Advanced Skin Protectant*

Before the first application of the Cavilon Advanced Skin Protectant (3M™ Health Care; Minnesota, USA) the skin needs to be cleaned with wound cleanser. An experienced nurse applied the new skin protectant twice weekly on the irradiated area. The product is applied as a liquid and it polymerizes as a film in 30 seconds.

The skin protectant consists of a combination of two chemicals; an acrylic tetrapolymer and a 2-octyl cyanoacrylate to create a durable film that adheres to moist and wet wounds and protects the skin from irritants, moisture, and friction. The skin protectant was tested on cytotoxicity, irritation, sensitization, genotoxicity, and systemic toxicity based on the criteria of expected use (>30 days in contact with a breached skin barrier) and guidance covering the biological evaluation of medical devices outlined in EN ISO 10993-1:2009 before applying the product on humans. The test results (not shown) demonstrated that the product is safe for its intended use.<sup>28</sup>

The bolus effect of Cavilon Advanced Skin Protectant in combination with external beam RT was evaluated at the LOC by an experienced physicist. Results demonstrated that the skin protectant does not cause any significant dose build-up or water equivalent properties when applied up to six layers when measured on water equivalent phantom material.

## **Outcome measures**

### *Patient data*

Clinical information regarding the patient's personal, disease- and treatment-related characteristics was collected via the patient's medical charts.

### *RTOG grading*

Clinically the severity of ARD was evaluated by the criteria of the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer (RTOG/EORTC).<sup>8</sup> The patient's pain was evaluated by using a Visual Analogue Scale (VAS) with a score grid ranging from 0 to 10 (no pain – a lot of pain).

## **Results**

### **Case report 1: control**

The patient is a 75-year old woman, with no known history of skin diseases or other comorbidities. She was diagnosed with an invasive spinocellular carcinoma on the left labia with a stage cT1b N2b M0 (2.5 by 1.5 cm) on the first of November 2016. A multidisciplinary team of gynaecologists, oncologists, and radiotherapists, decided to treat the tumour with radiochemotherapy based on the tumour and the patient's characteristics. The patient was treated with RT (25 x 1.8 Gy + 10 x 2 Gy; total dose 65 Gy over 35 fractions) alongside a concomitant weekly chemotherapy treatment based on Cisplatin from December 27<sup>th</sup> 2016 until February 15<sup>th</sup> 2017.

This patient received the institutional standard skin care protocol to prevent and manage ARD in the vulvar region. The timeline following the development of ARD in this patient is depicted in table 2. On RT fraction 8 (14.4 Gy), she complained of vaginal and anal irritation and therefore the wound care team started with the application of the Cavilon No Sting Barrier Film alongside the Kamillosoan sitz bath and the Cavilon Contenance Care Wipes. On RT fraction 22 (39.6 Gy), the patient developed a RTOG grade 3 ARD in her groins, alongside a grade 2A at the labia and perineum. An enzyme alginogel (Flaminal Hydro, Flen Pharma, Kontich, Belgium) in combination with a paraffin gauze dressing was applied on the patient's groins (Figure 1A). Towards RT fraction 32 (59 Gy), the skin reaction aggravated at the patients' perineum and therefore a Mepilex dressing was applied (Figure 1B). In overall the patient experienced a lot of pain (>8/10) due to the wounds during RT. At the final RT session, the patient still experienced moist desquamation in her groins and at her perineum (grade 2B). One week after the final RT session, the skin had healed well; the perineum and groins were dry, while the labia were softened. At a second follow-up, 14 days after the final RT session, the skin reactions had resolved towards a RTOG grade 1 (Figure 1C).

### **Case report 2: experimental**

The patient is an 81-year old woman, who has never smoked, has a normal weight, and does not consume alcohol. She has a sun-sensitive skin, which sometimes burns, and slowly tans to light brown (Fitzpatrick type 3), but she has no known skin condition. She suffers from black lung disease. On the first of April 2016, she was diagnosed with a spinocellular carcinoma on the right labia with a Stage pT1a N0 M0 (2 by 1 cm). A multidisciplinary team of gynaecologists, oncologists, and radiotherapists, decided to treat

the tumour with surgery on the 3<sup>rd</sup> of October 2016. On August 11<sup>th</sup> 2017, she was diagnosed with a recurrent vulvar carcinoma on the right labia. The multidisciplinary team decided to treat her with RT, which started the 9<sup>th</sup> of September 2017 and lasted until October 27<sup>th</sup>, 2017 (25 x 2 Gy with a planned 2 week interruption followed by 10 x 2 Gy boost; total dose 70 Gy over 35 fractions).

The patient received the institutional skin care from the beginning of RT alongside the Cavilon Advanced Skin Protectant. Table 3 shows the timeline and the patient's clinical course. On fraction 16 of RT (dose 32 Gy), the patient developed an RTOG grade 2A skin reaction in groins and an RTOG grade 3 on the right labia. From this time point, the novel skin barrier protectant, the Cavilon Advanced Skin Protectant, was applied on the affected and moist skin areas. Following the application of the skin protectant, the wounds did not aggravate and already at the fifth Cavilon Advanced Skin Protectant application (fraction 24/35) the wounds started to heal in her groins (Figure 2A). At the final RT session, her groins and labia showed a grade 2A skin reaction and her perineum was completely healed (Figure 2B). All the RT sessions were executed without the planned RT interruption. The wounds demonstrated complete closure 10 days post-RT (RTOG grade 1, Figure 2C). The patient was very satisfied with the overall skin care treatment and her overall pain score was 6/10 or lower during RT. She only mentioned a stinging feeling, when Cavilon Advanced Skin Protectant was applied to moist and open skin regions, which resolved shortly after the application. The two nurses that applied new skin protectant, were in general very satisfied with the rapid application time, the user-friendliness as it acts like a liquid dressing making it suitable for hard to dress areas like the sacrogenital area, and the eventual treatment outcome.

## Discussion

ARD remains a devastating side effect of RT and in particular for patients with a vulvar carcinoma due to presence of skin folds and the difficulty to manage the wound care in this anatomical region. To date, based on scientific evidence from systematic reviews, there is no consensus on which preventive and therapeutic treatment strategies are the most appropriate. As such, a lot of RT departments develop their own institutional skin care protocol based on clinical experience.<sup>23</sup>

In this case report study, two female patients with vulvar carcinoma treated with RT at the LOC were described. One patient received the standard institutional skin care protocol, while the other was treated with same protocol in combination with the Cavilon Advanced Skin Protectant. Both patients developed confluent moist desquamation during their RT course. However, after the application of the Cavilon Advanced Skin Protectant, the moist wounds started to heal during the RT course, which resulted in bright erythema at the final RT session. On the other hand, the patient who only received the standard skin care still presented patchy moist wounds in her groins at the end of RT. These results suggest that the Cavilon Advanced Skin Protectant enhanced the wound healing process of the RT-induced wounds.

A comparison between the two cases (control vs. experimental) was made concerning their pain, quality of life, and the total nursing costs in hospital (Table 4). The patient treated with standard protocol had in overall a higher maximum pain score (>9/10) in comparison with the patient treated with the novel skin protectant (6/10), which resulted in a stronger pain medication for the control patient. The mobility of control patient was also more limited than for experimental patient, as the control patient needed

transportation to the hospital via an ambulance, while the experimental patient could still walk during her RT course. The control patients also needed a home care nurse twice a day, while this was only once a day for experimental patient. The nursing costs in the hospital were higher for control patient than for the experimental patient due to a longer wound care time and a higher total wound care cost. These results demonstrate that Cavilon Advanced Skin Protectant could reduce the ARD-associated pain, and improve the patients' QOL. Moreover, the nursing time was reduced, which resulted in a decline of the wound care costs.

This is the first case report that investigates the use of Cavilon Advanced Skin Protectant in patients with ARD. Up to now, there was only one clinical study that investigated the new skin protectant in 16 patients with IAD. The product was applied twice weekly on damaged and moist skin up to 6 applications in total. They documented an overall improvement of the skin reactions of 96%. Four patients demonstrated complete reepithelialisation and 5 showed substantial improvement. There was also a substantial pain reduction for the all the 9 patients who reported pain at their enrolment <sup>29</sup>. Notwithstanding that the pathogenesis of IAD differs from ARD, these results are line with our case report study, demonstrating an improved wound healing and a reduction in pain.

This case report was not without limitations. Due to the small sample size, the reproducibility of the results is limited. The patient received Cavilon Advanced Skin Protectant twice weekly starting from a RTOG grade 2A-3 ARD. A twice-weekly application starting from the moment of moist desquamation might not be sufficient to keep the skin intact as the ionising radiation causes daily damage to the skin in the irradiated area. Therefore, future studies should investigate if an earlier starting point (e.g. RTOG grade 1)

and a higher frequency of weekly applications could improve the efficacy of Cavilon Advanced Skin Protectant. In some cases, Cavilon Advanced Skin Protectant can cause a stinging feeling on open wounds.

## **Conclusions**

The present study is the starting point for future clinical trials with a randomized controlled design and appropriate sample size, to test the actual efficacy of Cavilon Advanced Skin Protectant in the prevention and treatment of ARD in patients with cancer undergoing RT.

## **Acknowledgments**

### **Funding**

There was no funding for this case report study.

### **Conflict of interest**

The authors declare that they have no competing interests. The corresponding author, Leen Van Bever, has a speaker agreement with 3M.

### **Informed consent**

Informed consent was obtained from all individual participants included in the study.



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## Tables

Table 1: Radiation Therapy Oncology Group (RTOG) scoring for radiotherapy-induced skin reactions <sup>8</sup>

<b>RTOG grade</b>	<b>Grade 0</b>	<b>Grade 1</b>	<b>Grade 2A</b>	<b>Grade 2B</b>	<b>Grade 3</b>	<b>Grade 4</b>
<b>Description</b>	No change over baseline	Follicular, faint or dull erythema; epilation; dry desquamation; decreased sweating	Tender or bright erythema	Patchy moist desquamation; moderate oedema	Confluent, moist desquamation, other than skin folds; pitting oedema	Ulceration; haemorrhage; necrosis

Table 2: Timeline describing the development of ARD and wound care practices in the control patient

Time point	Event	Pain	RTOG grade
1 November 2016	Diagnosis of invasive spinocellular carcinoma of the left labia (Stage cT1b N2b M0)	NA	NA
8 December 2016	RT planning session (25x1.8Gy +10x2Gy boost, total dose 65 Gy)  Information on standard skin care practices	NA	NA
27 December 2016  Fraction 1/35	Start of radiotherapy + application standard skin care	NA	NA
9 January 2017  Fraction 9/35	Patient complains about vaginal irritation  Standard skin care (including Cavilon No Sting Barrier Film + Kamilloosan sitz bath +  CavilonContinence Care Wipes)	NM	NM
23 January 2017  Fraction 19/35	Standard skin care  +  Mepilex on the groins	NM	Labia: 1  Groins: 2A  Perineum: 1

30 January 2017 Fraction 23/35	Standard skin care + Enzym alginogel + paraffin gauze dressing in groins	8/10	Labia: 2A Groins: 3 Perineum: 2A
1 February 2017 Fraction 25/35	Standard skin care + Enzym alginogel + paraffin gauze dressing in groins	9/10	Labia: 2A Groins: 3 Perineum: 2A
2 February 2017 Fraction 26/35 (1 <sup>st</sup> boost)	Placement of bladder catheter Standard skin care + Enzym alginogel + paraffin gauze dressing in groins	9/10	NM
10 February 2017 Fraction 32/35 (7 <sup>th</sup> boost)	Standard skin care + Enzym alginogel + paraffin gauze dressing in groins + Mepilex on perineum	NM	Labia: 2A Groins: 3 Perineum: 2B



15 February 2017 Final RT session Fraction 35/45 (10 <sup>th</sup> boost)	Standard skin care  +  Enzym alginogel and paraffin gauze dressing in groins  +  Mepilex on perineum	6/10	Labia: 2A  Groins: 3  Perineum: 2B
23 February 2017  7 days post –RT	Standard skin care	NM	Labia: 2A  Groins: 2B  Perineum: 1
3 March 2017  14 days post-RT	Standard skin care	NM	Labia: 1  Groins: 1  Perineum: 1

*NA, not applicable; NM, not measured; RT, radiotherapy; RTOG, Radiation Therapy Oncology Group*

Table 3: Timeline describing the development of ARD and wound care practices in the experimental patient

<b>Time point</b>	<b>Event</b>	<b>Pain</b>	<b>RTOG grade</b>
1 April 2016	Diagnosis of spinocellular carcinoma of the right labia (Stage pT1a N0 Mo)	NA	NA
3 October 2016	Hemivulvectomy with an unilateral inguinal lymphadenectomy	NA	NA
11 Augustus 2017	Recurrence of the vulva carcinoma		
30 Augustus 2017	RT planning session (25x2Gy +10x2Gy boost, total dose 70 Gy)  Information on standard skin care practices	NA	NA
9 September 2017  Fraction1/35	Start of radiotherapy + application standard skin care	NA	NA
28 September 2017  Fraction 16/35	1 <sup>st</sup> application of Cavilon Advanced Skin Protectant	4/10	Labia: 3  Groins: 2A
2 October 2017  Fraction 18/35	2 <sup>nd</sup> application of Cavilon Advanced Skin Protectant	5/10	Labia: 3  Groins: 3  Perineum: 3

5 October 2017 Fraction 21/35	3 <sup>rd</sup> application of Cavilon Advanced Skin Protectant	6/10	Labia: 3 Groins: 3 Perineum: 3
9 October 2017 Fraction 21/35	4 <sup>th</sup> application of Cavilon Advanced Skin Protectant	6/10	Labia: 3 Groins: 3 Perineum: 3
12 October 2017 Fraction 23/35	5 <sup>th</sup> application of Cavilon Advanced Skin Protectant	6/10	Labia: 2B Groins: 2B Perineum: 2B
16 October 2017 Fraction 26/35 (1 <sup>st</sup> boost)	6 <sup>th</sup> application of Cavilon Advanced Skin Protectant	3/10	Labia: 2B Groins: 2B Perineum: 2B

23 October 2017 Fraction 31/35 (6 <sup>th</sup> boost)	7 <sup>th</sup> application of Cavilon Advanced Skin Protectant	NM	Labia: 2B Groins: 2B Perineum: 2B
26 October 2017 Fraction 34/35 (9 <sup>th</sup> boost)	8 <sup>th</sup> application of Cavilon Advanced Skin Protectant	5/10	Labia: 2B Groins: 2B Perineum: 2B
27 October 2017 Fraction 35/45 (10 <sup>th</sup> boost)	Final RT session	5/10	Labia: 2B Groins: 2B Perineum: 2B
30 October 2017 3 days post-RT	9 <sup>th</sup> application of Cavilon Advanced Skin Protectant	4/10	Labia: 2B Groins: 2B Perineum: 2B
2 November 2017 6 days post-RT	10 <sup>th</sup> application of 3M™ Cavilon™ Advanced Skin Protectant	0/10	Labia: 2A Groins: 2A Perineum: 2A

6 November 2017  10 days post-RT	11 <sup>th</sup> application of Cavilon Advanced Skin Protectant (final)	0/10	Labia: 2A  Groins: 2A  Perineum: 2A
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*NA, not applicable; NM, not measured; RT, radiotherapy; RTOG, Radiation Therapy Oncology Group*

Table 4: Comparison on pain, quality of life, and in hospital costs between the standard skin care and the 3M™ Cavilon™ Advanced Skin Protectant protocol

	<b>Standard of care</b>	<b>Cavilon Advanced Skin Protectant</b>
Medication*	Started with a non-opioid + opioid for mild to moderate pain (step 1-2)  Eventually progressed to opioid for severe pain (step 3)	Non-opioid (step 1)  If needed, opioid for mild to moderate pain (step 2)
Transportation	Ambulance	Walking
Max pain score	> 9/10	6/10
Home nurse	2x/day → washing, wound care, bladder catheter, medication	1x/day → washing, bladder catheter  (Already started before RT)
Total costs	+/- € 380	+/- € 209,20
Total hours care (in hospital)	20 min/care x 25 days → +/-500 min	10 application = 10 min + 10 control visits= 5 min  → +/- 150 min

\* WHO analgesic ladder (<https://www.who.int/ncds/management/en/>); RT, radiotherapy; WHO, World Health Organisation

## **Figure legends**

**Figure 1: Development of acute radiodermatitis in a patient that underwent with radiotherapy for vulvar cancer and received the institutional standard skin care.**

(A) She presented a RTOG grade 3 acute radiodermatitis at her labia, groins and perineum at radiotherapy fraction 24 of 35. (B) At fraction 32 of 35, she still presented a RTOG grade 3 at her labia, groins and perineum. (C) At follow-up, 14 days post-radiotherapy, the wounds improved, resulting in a RTOG grade 1 skin reaction.

**Figure 2: Development of acute radiodermatitis in a patient that underwent with radiotherapy for vulvar cancer and received the institutional standard skin care in combination with Cavilon Advanced Skin Protectant.**

(A) She presented a RTOG grade 2B acute radiodermatitis at her labia, groins and perineum at radiotherapy fraction 25 of 35. (B) At fraction 31 of 35 she presented a RTOG grade 2B acute radiodermatitis at her labia, groins and perineum. (C) At follow-up, 14 days post-radiotherapy, the wounds improved, resulting in a RTOG grade 1 skin reaction.