Observational study of SorbaView® 2000, SorbaView® Ultimate and SecureView® Port AFZ Dressings used on Central Venous Catheters in Eleven Italian Oncology, Hematology and Pain Centers

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Abstract

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Dressing care is one of the nursing challenges that is more and more frequent in the management of central venous catheters (CVCs). Our intention with this observational study was to study the efficacy and tolerability of the latest generation devices recently introduced in Italy. The study was performed on 435 patients; including 293 carriers of totally implantable CVCs and 142 carriers of tunneled and non-tunneled CVCs. In 90% of 311 patients with scheduled therapy of greater than seven days, the dressing adhered completely, at the end of seven days and up to 10 days. In 10% of all 435 patients the dressing became partially detached at between greater than one day and less than 10 days, but not enough to justify dressing change. Of the 10% that partially detached with dwell time greater than one day and less than four days, most occurred in Hematology. A cumulative total of 1,391 dressings were applied.

At the conclusion of the study, 84% of patients reported that they were satisfied with the use of the SorbaView 2000, SorbaView Ultimate and SecureView Port AFZ dressings.

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Central venous catheters (CVCs) are extremely important devices in the management of patients who must undergo chemotherapy treatment (Oncology Nursing Society (ONS), 2004), bone marrow transplant, parenteral nutrition, transfusions and analgesic therapies (Centers for Disease Control (CDC), 2000). The use of these three types of CVCs has increased considerably over recent years in order to reduce the incidence of extravasations and to preserve the venous characteristics of the patient. At the same time, the increase in the use of CVCs creates new problems including the prevention of possible infections. In immunodeficient patients, the nurse must pay particular attention to skin hygiene (Larson, 2001) and use and adopt suitable behaviour to lower the microbial load. Consequently, ever-increasing competencies are required of nurses who manage the dressing care of CVCs (Gillies, et al., 2003; Hoffman, Weber, Samsa, and Rutala, 1992; Shivan, et al., 1991; Woods, Nass, and Deisch, 2000). In consideration of our desire to meet and comply with the Atlanta 2002 CDC Guidelines (O’Grady, et al., 2002) on Italian multi-center observational study was planned using new, advanced feature CVC dressings recently introduced in Italy: SecureView Port AFZ, a specialized implanted port dressing with a small adhesive free zone over the noncoring needle area; SorbaView Ultimate high MVTR dressing; and standard SorbaView 2000 dressing. The dressings are manufactured under the Centurion® brand by Tri-State Hospital Supply Corp., Howell, MI, USA. SecureView Port AFZ dressings were selected for use over noncoring needles inserted cutaneously into implanted infusion ports on 293 patients. Two different dressing sizes were used. Two different geometric sizes and shapes of SorbaView Ultimate dressings were used at jugular and PICC sites on 27 patients. Three sizes of SorbaView 2000, appropriate in shape for anatomical insertion site and type/size/configuration of vascular access catheters being used, were applied to 115 patients. These seven code numbers from three families of SorbaView dressings were selected as being able to accommodate all foreseen vascular access devices’s (VAD’s) clinical situations for all patients, all anatomical insertion sites, and all VAD configurations (size, shape, lumen count, safety noncoring needle superstucture, pigtais, etc). Dressings were selected appropriately to fit the clinical situation.

Nursing teams from 11 oncology and hematology centers for adults in central and northern Italy participated in the study. Each center had a designated study coordinator.

Objectives
- Examine the comfort of patients resulting from the SorbaView and SecureView dressings.
- Evaluate the incidence of infections.
- Monitor the average duration of dwell time of the dressings.

Methods, Materials, Conditions

1. Patients, Consent, Enrollment, Skin Lesion Exclusion, ECOG (Eastern Cooperative Oncology Group) Scale of Skin Toxicity, Study Size

All patients were informed verbally by study center professional nurses of the intent to use SorbaView and/or SecureView dressings on them as part of a dressing study; patients gave their verbal consent to the use of the new dressings. (Note: professional nurses in Italy are authorized by their directors/chief physicians of their operational units to obtain patient verbal consent for study purposes.)

Inclusion criteria: Carriers of totally or partially implantable CVCs, without active skin lesions at the site of insertion, subject to autotransplant of staminal cells and high-dose chemotherapy, pain therapy, radio and chemotherapy, and plasmapheresis.

Exclusion criteria: Documented infection at the site of insertion with major skin lesion (Grade 2 – 3 according to the ECOG scale of skin toxicity – Table 1), with GvHD (Graft versus Host Disease), with haemorrhages at the site of insertion or with dislocation of the CVC.

Patients were divided into two groups according to the type of catheter:
- 293 patients who are carriers of totally implantable CVCs (67.35%)
- 142 patients who are carriers of tunneled and non-tunnelled CVCs (32.65%)

2. Three dressing products were used: SorbaView 2000, SorbaView Ultimate and SecureView Port AFZ – Basic Structure and Differences:

SorbaView 2000 is a highly permeable, transparent film dressing. This medical device is manufactured with a breathable and highly moisture vapor permeable polyurethane film layer that creates an occlusive barrier to external agents, microorganisms, and infection sources. An absorbent cellulose pad leaves the site dry, reducing the number of dressing changes and bacterial

<table>
<thead>
<tr>
<th>Grade</th>
<th>Symptom or Visual Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Scattered macular or papular eruption or asymptomatic erythema</td>
</tr>
<tr>
<td>2</td>
<td>Scattered macular or papular eruption or erythema with pruritus or other associated symptoms</td>
</tr>
<tr>
<td>3</td>
<td>Generalized symptomatic macular, popular, or vesicular eruption</td>
</tr>
<tr>
<td>4</td>
<td>Exfoliative dermatitis or ulcerating dermatitis</td>
</tr>
</tbody>
</table>

Note: During the planning phase of the study, the group explained the references of the Grades in further detail: Grade 0 means healthy, intact skin without signs of phlogosis; Grade 1 means the presence of hyperemia greater than 1 centimeter at the exit point of the CVC +1-fibrin; Grade 2 means greater than 1 and less than 2 centimeters at the point of exit of the CVC +1-fibrin; Grade 3 means hyperemia, secretion, pus. +1-fibrin. Grade 4 was not defined as it had been established that the patient would have already abandoned the study with grade 2 or 3.

Background:

中央静脉导管（CVCs）对于需要化疗治疗的患者、骨髓移植、肠外营养、输血和镇痛等治疗至关重要。在未来几年中，CVCs的数量显著增加，以降低外渗的发病率并保持静脉的特性。对于免疫缺陷的患者，护士必须特别注意皮肤卫生（Larson, 2001），并使用适合的手段来降低微生物的载量。因此，对于CVCs的护理需要不断提高护理人员的技能。

研究方法、材料和条件

1. 患者、同意书、入组、皮肤損害排除、ECOG（东部合作肿瘤学群体）皮肤毒性量表，研究大小

所有患者都由中心研究的执业护士口头告知使用SorbaView和/或SecureView敷料的意图；患者同意使用新敷料。注意：意大利的执业护士由其医疗机构的院长/首席医学专家授权进行患者的口头同意。

包括标准：完全或部分植入式CVC的携带者，皮肤未损伤于插入部位，接受自体移植的干细胞细胞和高剂量化疗，疼痛治疗，放疗和化疗，以及血浆置换。

排除标准：感染部位有明显皮肤损伤（根据ECOG皮肤毒性量表表1中的2-3级），GVHD（移植物对抗宿主疾病），出血或CVC移位。

患者被分为两组，根据导管的类型：
- 293例完全植入式CVC患者（67.35%）
- 142例植入式和非植入式CVC患者（32.65%）

2. 三种敷料产品被用于使用：SorbaView 2000，SorbaView Ultimate和SecureView Port AFZ——基本结构和差异：

SorbaView 2000是一种高度透气的透明胶布敷料。这种医疗设备由透湿透气的聚氨酯薄膜层制成，能够封住外部环境中的生物和微生物，减少敷料更换的次数和细菌污染。
83.90% of patients approved the new dressings because:

- Patients could perform thorough daily hygiene (shower) due to dressing adhesion
- Patients could carry out daily and sports activities
- Patients reported the absence of skin reactions in case histories where they have intolerance to other dressings
- Improvement of the quality of life

11.27% of the sample who expressed criticism reported:

- Feeling of lack of stability of the noncoring needle in patients who were implanted port carriers
- Type of CVC (Secalon®) in supraclavicular position (difficulty shaving due to the high position of the dressing)
- Transparency of dressing for those patients used to using non-transparent dressings (This type of patient does not want to see the exit point of catheter from skin)

**Discussion and Conclusion**

Data obtained from this observational study makes it possible to draw several objective conclusions regarding the dressings used in this study, as well as some logically following subjective inferences.

In the first place, dressing dwell time is satisfactory and compliant with Atlanta CDC Guidelines. No minimum dwell times for dressings are set in these guidelines. Obviously, the longer dwell time that is free of troubles, the better it is for patient, nurse, hospital, economics, and health care system generally.

The good dressing dwell time is also associated with a high degree of dressing adhesion, as the total number of dressings that became detached (0.57%) or partially detached (6.75%) is small. Further, the partially detached dressings were not sufficiently loose to justify an unscheduled dressing change, as catheter security and contamination barriers were still intact. It is important to note that no other ancillary securement devices, such as stand alone anchors or tapes, were used under or on the dressing, near it, or on the patient as supplementary catheter holding; merely the two dressing parts included in each individual, sterile unit dressing package were used in studied patients. This study shows, by not having them present, that such costly additional measures are not needed to achieve long dressing dwell times.

Regarding the safety profile, the objective reporting of the skin conditions observed at the dressing showed a slight tendency to the development of major lesions. These observations were limited to hematology patients in cases that allow a certain degree of prognosis for this complication.

Only 4.83% of patients had to abandon the study due to criticality. However, several of these patients were subjected to treatment with MOAB (monoclonal anti-EGFR antibodies), and therefore subject to dermatologic toxicity unrelated to dressings as a cause, especially in view of the long dressing dwell times achieved. Others, affected by hematological neoplasias, and therefore subject to prolonged and severe neutropenias, have a high risk of infection regardless of the dressing's presence or not, or the timing and interval of the dressing changes (Rasero, et al., 2000).

From the subjective viewpoint a large number of patients (84%) were satisfied with the functionality of the dressings studied.

Thirty-two patients were enrolled by the Centre of Analgesic Therapy in Genova. Of these, 23 patients who carried epidural catheters were able to maintain the epidural catheter; and the absorbent pad of the dressing in place made it possible to keep the point of insertion dry and sterile.

The results of this observational study for long dressing dwell time, high dressing adhesion with a very low level of skin issues, in this susceptible patient population of oncology (Zitella, et al., 2006) and hematology, enable us to sustain a good profile of efficacy, tolerability and safety and to make some logical inferences and conclusions on the following clinical parameters:

- Visibility of the site of insertion
- Decrease of admittances to day hospital and/or sterile rooms (longer dressing dwell times mean patient does not have to come back to hospital for dressing change as frequently)
- Optimization of nursing time (International Nurse Counsel, 2006) (greater number of days of dwell time of the dressing means fewer dressing changes and less labor)
- Decrease in dressing and dressing change material costs (use of fewer dressings due to longer dwell times; dressings, dressing change trays and other materials needed are directly related to dressing dwell time)
- Decrease in the risk of contamination of the insertion site (greater number of days of dwell time of dressing; every time a dressing is changed, the entire insertion site wound and catheter lumen is exposed to potential contamination increasing the infection potential for what is already the most compromised group of VAD/dressing patients)

Note: No quantitative data was collected on the above four parameters. It is merely authors' logical deductions.

Further comparative studies with other devices could be useful in the future in order to improve the management of these delicate, most susceptible patients. Using new products and technologies to optimize the competencies and techniques of colleagues on the basis of evidence based nursing (EBN) makes it possible to tackle difficult and intractable daily problems in the management of onco-hematological patients.

**Acknowledgements and Contributions**

Authors wish to thank Praesidia S.r.L for multi-study center management activity, translation activity, and for coordination with Tri-State Hospital Supply Corp. in USA to accomplish publication in English in JAVA.

**Conflict of Interest Statement**

The authors of this study have no financial interest in the products used in this study.

**Support for the Study Statement**

Dressing materials for this study were kindly provided free of charge by the Italian medical device company, Praesidia S.r.L.

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proliferation. An external top layer of non-woven fabric adds body to the film, prevents film from wrinkling and sticking to itself during application, creates a central site viewing window, and is comfortable to touch and wear for the patient. The dressing can be positioned with only one hand and has a dwell time that can reach up to seven days (Lee, 2002). The pre-cut tape adapts to the skin and to the patient’s anatomy.

Three sterile dressing code numbers of SorbaView 2000 were used on 115 patients by type of catheter and insertion site:
• SV40XT: 79 patients, CVC tunneled and non tunneled, subclavian
• SV48VXT: 24 patients, epidural
• SV30NXT: 12 patients, CVC tunneled

SorbaView Ultimate includes the features of SorbaView 2000, but has an approximately two times higher MVTR (moisture vapor transmission rate), with sizes, features, and geometric shapes to adapt to difficult internal jugular and PICC insertion sites. Two sterile SorbaView Ultimate dressing code numbers were used on 27 patients by type of catheter and insertion site:
• SV44UXT: 21 patients, CVC jugular
• SV60UXT: 6 patients, PICC

SorbaView 2000 and SorbaView Ultimate dressings were used on the following five manufacturers of CVC, PICC, and epidural catheters:
• Becton Dickinson Secalon™ Seldy 16G single lumen
• Becton Dickinson Logicath™ 14G dual lumen
• C.R. Bard®, Inc., 9FR
• B.Braun Medical, Inc.
• Medtronic, Inc., Epidural
• Arrow® International, Inc., 7FR and 12 FR triple lumen

SecureView Port AFZ includes the higher MVTR of SorbaView Ultimate, but does not include an absorbent pad because exudate leaks at noncoring needle insertion sites are not frequent. Instead, an adhesive free zone is present in a small round or oval area of the film window to permit dressing removal from all types of noncoring needle sheathing safety mechanisms without prematurely, or accidentally, activating the safety mechanism. Two sterile SecureView Port AFZ dressing code numbers were used on 293 patients:
• SCVP44XT: 99 patients
• SCVP66XT: 194 patients

Four manufacturers of implanted ports were used:
• B.Braun Medical, Inc., Celsite® ST 305 6.5FR
• C.R. Bard®, Inc., 8FR, 6.6FR, 9FR
• Tyco® Healthcare Inc., 9FR
• AngioDynamics, 9FR

Four types/manufacturers of noncoring needles were used:
• C.R. Bard®, Inc., Huber Needle 19Ga, 20Ga
• C.R. Bard®, Inc., Huber Plus 20Ga
• Sevit Gripper® 19G
• Smiths Medical MD, Inc., Gripper

3. Clinical Study Centers’ Protocols, Catheter Descriptions and Skin Antiseptic
Each center already had an official protocol elaborated and in practice for managing the nursing of CVCs with references to the recommendations of the Atlanta 2002 CDC Guidelines (CDC 2000; O’Grady, et al., 2002) in which full compliance by nursing staff was guaranteed.

For the purpose of this study, CVCs have been divided into two different categories:
• Totally implantable port CVCs, on which was used SecureView Port AFZ transparent fabric border dressings with a small non-adherent zone centered in the gas permeable transparent polyurethane window (SCVP44XT and SCVP66XT).
• Tunneled and non-tunneled CVCs (short-term, Hohn, with high flow for apheresis, supraclavicular Becton Dickinson Secalon™, C.R. Bard® Groshong®, Epidural) on which was used SorbaView 2000 and SorbaView Ultimate gas permeable transparent window dressings with absorbent pad
and fabric border (SV30NXT, SV40XT, SV44UXT).
- Epidural catheters for analgetic therapy, on which was used SorbaView 2000 gas permeable transparent window dressings with absorbent pad and fabric border (SV40XT, SV48VXT).

Only one type of skin antiseptic cleaning agent was used—PVP Povidone Iodine. No liquid skin protectant barriers were used. A liquid skin barrier can greatly weaken the adhesion of any dressing by substituting itself for the dressing's adhesive and interposing itself between the skin and the dressing's adhesive. The SorbaView dressing line is known to have a history of use in the USA with very few skin issues (Lee, 2002; Penney-Timmons, 2005; Trotter, Brock, Schwaner, Conaway, and Burns, 2008; Winfield, Davis, Schwaner, Conaway, and Burns, 2007; Garcia, Jendresky, Landesman, Maher, and Nicolas, 2003).

4. Operators
Nurses at each center were trained in the correct technique of dressing application and removal before enrollment of the patients:
- Interval times between two dressing changes was from 3 to 7/10 days depending on patient's course of therapy, end of therapy, and other variable situations.
- The number of dressings envisaged per patient for the study was three; however in some cases it was actually four or five dressings due to extended therapy, a particular type of therapy, or because some patients specifically requested that a SorbaView dressing continue to be used on them, despite three being attained.
- Familiarity with the ECOG scale of skin toxicity in detail (Table 1)

5. Data Collection
The group produced three types of cards containing data collection:
- Patients and type of CVC
- Interval between two dressing changes
- Skin condition around the point of insertion of the CVC (ECOG scale of skin toxicity) or noncoring needle
- Therapeutic treatment
- Interview with the patient on comfort with particular reference to daily hygiene

Results
The 435 patients enrolled from September to December 2007 were distributed as follows:
- San Martino Genova Medical Oncology Unit: 54 patients
- Galliera Genova Antalgic Therapy Centre Unit: 32 patients
- Galliera Genova Oncology Unit Day Hospital: 50 patients
- Piacenza Hematology Single Speciality Unit and Oncology Unit Day: 33 patients
- Regina Elena Roma Hematology Unit: 40 patients
- S. Paolo Savona Medical Oncology Unit: 43 patients
- G. Rossi Verona Oncology Unit Day Hospital: 46 patients
- Niguarda Milano Hematology Unit: 44 patients
- S. Croce Moncalieri Oncology Unit Day Hospital: 22 patients
- Vicenza Oncology Unit Day Hospital: 39 patients
- San Polo Monfalcone Medical Oncology Unit Day Hospital: 32 patients

Of the 435 patients enrolled, 414 (95.17%), completed the study.

Of the 435 patients, 21 (4.83%), abandoned the study due to:
- Pruritus: three patients (0.69%)
- Perspiration: two patients (0.46%)
- Dressing allergy: three patients (0.69%)
- Eythema and redness: five patients (1.15%)
- Infiltration/Sepsis/Death: eight patients (1.84%)

Of a total of 435 patients the dressing dwell time was:
- 116 patients (26.7%) ≤ three days (according to therapeutic schedule)
- 311 patients (71.5%) ≥ seven days (according to therapeutic schedule)
- Eight patients (1.84%) abandoned the study (Reason: infection of Grade 2 or 3, intolerance, death)

Adhesiveness of the dressing (435 patients treated):
- In 390 patients (89.65%) the dressing adhered completely
- In 40 patients (9.19%) the dressing is partially detached, but did not justify changing
- In five patients (1.15%) the dressing is detached (Reason: difficult chemotherapy or skin problems)

1391 dressings were applied:
- 1289 adhered (92.66%)
- 94 were partially detached (6.75%), but did not justify changing dressing
- Eight were detached (0.579%) (Reason: difficult chemotherapy or skin problems)

Of the 435 patients under observation, the condition of the skin at the point of insertion of the CVC or noncoring needle was noted according to the ECOG scale (Table 1). The observation was performed daily and the finding reported on the card, at the time of application and upon removal of the dressing, until the end of the study.

At the first application:
- 422 patients (97.01%) presented with Grade 0
- 13 patients (2.99%) Grade 1
At the end of the study:
- 413 (94.94%) patients presented with Grade 0
- In 22 (5.06%) patients the point of insertion of the CVC showed an evolution of the Grade of the skin up to Grade 2 and 3 on the ECOG scale

Comfort of the 435 patients:
- 365 (83.90%) expressed approval
- 49 patients (11.27%) were critical (see following bullets)
- 21 patients (4.83%) abandoned the study for the above-mentioned reasons
83.90% of patients approved the new dressings because:

- Patients could perform thorough daily hygiene (shower) due to dressing adhesion
- Patients could carry out daily and sports activities
- Patients reported the absence of skin reactions in case histories where they have intolerance to other dressings
- Improvement of the quality of life

11.27% of the sample who expressed criticism reported:

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Pictures and detailed descriptions of the dressings studied are not included herein, but are viewable at www.tshsc.com.

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Lee, M. (2002). Seven day dwell times for vascular access device exit site dressings. INS National Convention Poster Presentation May 7, 2002 by Michele Lee in Phoenix, AZ. Reprints of study available from Tri-State Hospital Supply Corporation, Howell, MI.


