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HAL Authorization

1 **Evaluation of the impact of pharmacist-led educational intervention on knowledge and**
2 **skills of cancer patients with Totally Implantable Venous Access Port: a single-center,**
3 **non-randomized controlled study**

4

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35 **Summary**

36 **Background**

37 Totally Implantable Venous Access Port (TIVAP) is a type of implantable medical device that
38 enables repetitive access to the intravenous system through use of a Huber needle. This device
39 facilitates the administration of aggressive or long-term treatments while ensuring the comfort
40 and safety of the patient. To ensure proper use of the medical device and lower the risk of
41 complications, it is essential that patients acquire the necessary knowledge and skills
42 regarding the TIVAP.

43 **Objective(s)**

44 The main objective of the study was to assess the impact of a pharmaceutical interview (PI)
45 on patient's knowledge and skills for patients with TIVAP.

46 **Methods**

47 To achieve this goal, a pharmaceutical interview guide and an 18-item questionnaire were
48 developed, based on a 3 parts competency framework (knowledge, know-how, attitudes)
49 previously constructed by a multidisciplinary team. The intervention consisted of a
50 pharmacist-led interview with every patient on the day of the TIVAP insertion. Patients in the
51 control group received usual care. Patients included were interviewed by telephone 14 days
52 after implantation. Chi-squared tests were conducted to compare the scores obtained by each
53 group.

54 **Results**

55 The average score obtained by the control group (n=30) was 8.97, while the intervention
56 group (n=59) achieved an average score of 12.66 (p<0.001). The intervention group
57 demonstrated a significant increase in correct responses for all items, with eight questions
58 displaying significantly higher scores. Six of these pertained to theoretical knowledge, one to
59 know-how and one to attitudes.

60 **Conclusion**

61 These interviews clearly had an impact on the knowledge and skills of TIVAP patients.

62

63 **Key messages**

64 What is already known on this topic: To ensure the proper use of TIVAP and mitigate the risk
65 of complications, patient must acquire the necessary knowledge and skills.

66 What this study adds: This study makes a unique contribution to the existing literature on
67 patient's education by focusing on the impact of pharmaceutical interviews on patients with a
68 TIVAP. The interview with the pharmacist, which consisted of providing information on the
69 use of the device, its maintenance and potential complications, helped to improve patients'
70 understanding and self-management skills.

71 How this study might affect research, practice or policy: Future research is required to
72 examine the enduring retention of knowledge several months following the interview, and its
73 effect on patient outcomes, notably the frequency of complications.

74

75 **Keywords:** Totally implantable venous access port, patient education, pharmaceutical
76 interview

77 Introduction

78 Totally Implantable Venous Access Port (TIVAP), often referred to as Port-A-Cath, are
79 medical devices used to administer chemotherapies, blood products and parenteral nutrition
80 directly into a patient's bloodstream. TIVAP are commonly used in the management of
81 cancer, chronic pain, and other chronic conditions requiring frequent administration of
82 medications. It enables repeated access, up to 2,000 injections per TIVAP. Due to their cost-
83 effectiveness in healthcare management, relative to the overall cost of treatment, the use of
84 TIVAP has increased in the last decades [1]. In France, the latest available data estimates an
85 approximate 40,000 TIVAP insertion procedures being carried out annually [2]. TIVAP offer
86 multiple benefits, including preserving venous capital and reducing the risk of extravasation,
87 consequently improving safety and comfort to patients and healthcare providers [3,4]. These
88 devices are generally inserted under local anaesthesia in the operating room. The incidence of
89 complications related to central venous access is low compared to other long-term venous
90 access devices [5,6]. However around 10-13% of TIVAP insertions or use are associated with
91 complications [7,8]. Early complications may include local hematoma, wound dehiscence,
92 pneumothorax, or gas embolisms [9], while late-stage complications may comprise venous
93 thrombosis, infection, extravasation, or skin necrosis [3,10–12].

94 To reduce the risk of complications or improve their prompt resolution, patients with TIVAP
95 must acquire knowledge and skills about the device including safety skills: knowing what
96 post-operative care is necessary, knowing what complications could arise and, above all,
97 knowing how to react if these complications arise: knowing how to alert and identify the
98 caregiver to notify depending on the problem. Using TIVAP can thus be challenging for
99 patients, who may require extensive education and support to manage their device and
100 medications effectively.

101 Pharmacists are uniquely positioned to provide medication-related education, monitor drug
102 therapy, and collaborate with other healthcare providers to ensure that patients receive the
103 best possible care. In particular, pharmacist-led interventions, such as medication therapy
104 management (MTM) or pharmaceutical interviews, have been shown to improve patient
105 knowledge and self-management skills in other chronic diseases, such as diabetes,
106 hypertension, and asthma [13–15]. These interviews provide an invaluable opportunity for
107 communication between patients and pharmacists during which the latter can offer advice and
108 provide education and prevention messages to the patient [16]. In hospitals, these interviews
109 often take place on clinical wards and are based on a genuine pedagogical approach that
110 involves a prior assessment of the patient’s needs and representations [17]. Most of the time,
111 these interviews focus on drug therapy management. However, the literature rarely describes
112 the involvement of pharmacists in managing medical devices described, and particularly
113 TIVAP. Given the important role that pharmacists play in cancer care, it is important to
114 consider how they can contribute to the safe and effective management of these devices, and
115 how they can support patients in using them effectively. This is why pharmaceutical
116 interviews for patients with TIVAP were set up in our hospital.

117 To date, there is no evidence regarding the impact of pharmacist-led interventions on patients
118 with TIVAP. Therefore, this study aims to evaluate the impact of a pharmacist-led interview
119 on the knowledge and skills of patients with a TIVAP. Our hypothesis is that a pharmacist-led
120 interview will lead to significant improvements in patient knowledge and self-management
121 skills.

122 **Materials and methods**

123 **Study design and sample**

124 This prospective single-center, non-randomized controlled study was conducted in a French
125 university hospital from June 2021 to February 2022. Inclusion criteria required participants
126 to be over 18 years of age and have had their first totally implantable venous access port
127 (TIVAP) placement for cancer treatment. Exclusion criteria were established for individuals
128 who were unable to participate in an interview or answer a questionnaire by telephone due to
129 cognitive impairment or a language barrier. This research study was conducted in two distinct
130 stages: the first stage encompassed patient selection and evaluation specifically within the
131 control group, from June 2021 to August 2021. Subsequently, the second stage consisted of
132 patient selection and evaluation in the intervention group, from September 2021 to February
133 2022. Patients who met the eligibility criteria were approached for participation in the study at
134 the time of their TIVAP placement. Informed consent was obtained from each participant
135 prior to inclusion. The study was conducted in accordance with French regulations and was
136 approved by the Institutional Review Board of the *Groupe Nantais d’Ethique dans le*
137 *Domaine de la Santé* (n°GNEDS20210609).

138 **Intervention**

139 Patients in the intervention group participated in a pharmaceutical interview on the day of
140 their TIVAP placement (before or after the procedure) in the ambulatory surgery unit. A
141 pharmacist provided a face-to-face interview (approximately 30 minutes’ duration) to the
142 patients using an interview guide. This pharmaceutical interview guide was based on a
143 previously published work which consisted in the multi-professional elaboration of a
144 competency framework [18] for patients with a TIVAP [19]. It aimed improving patient
145 knowledge and comprehension of their TIVAP, including its use, maintenance, and potential
146 complications, as well as improving patient self-management skills, such as symptom

147 recognition, and appropriate use of the TIVAP. Patients in the control group received standard
148 care, i.e. the placement of the TIVAP without a pharmaceutical interview. No information
149 was given by the surgical team or nurses.

150 **Questionnaire**

151 To assess patient's knowledge and skills, a questionnaire was administered to patients by
152 telephone 14 days (+/- one day) after the intervention. This questionnaire assessing the
153 patient's knowledge and skills was based on the competency framework [19]. It consisted of
154 18 questions. Eleven questions assessed theoretical knowledge of the medical device,
155 management, adverse effects or warning signs and daily life. Four questions assessed know-
156 how, being the decision-making and action skills in various situations, including
157 complications, dangerous situations, and scar maintenance. Three questions assessed
158 attitudes, being daily management skills and implementation of adaptation capacities such as
159 being able to communicate about the medical device or to react accordingly to the situation.
160 The question headings are presented in Table 2. For each question, the research pharmacist
161 gave one point if the competence was considered acquired and zero point if it was not. In this
162 case, the research pharmacist gave the correct answer to the patient and provided him with
163 explanations. The sum of the points for each question gave an overall score out of 18 points.

164 **Endpoint**

165 The primary endpoint was the comparison of the overall mean scores obtained in each group.
166 We hypothesized that the mean overall score obtained in the intervention group would be
167 different from that in the control group. The secondary endpoints were the comparison of the
168 mean scores for each question between the two groups. We hypothesized that the mean scores
169 for each item in the intervention group would be different from those in the control group.

170 **Statistical analyses**

171 Quantitative variables were described using means and standard deviations (SD). Categorical
172 variables were described using the numbers and percentages of patients. Student *t*-tests were
173 used to compare the means of the quantitative variables and chi-squared tests, or Fisher's test
174 (small sample) were used to compare the categorical variables. P-values < 0.05 were
175 considered as significant for all analysis. The statistical analyses were carried out bilaterally.

176 Results

177 Participants

178 One hundred and twenty-five eligible patients agreed to participate in the study. Analyses
179 were performed on 89 patients: 30 in the control group and 59 in the intervention group. 26
180 patients were excluded from the analyses because they were not reachable by phone at the
181 time of the questionnaire (Figure 1).

182 Characteristics of patients

183 The characteristics of the patients are presented in Table 1. In both groups, about half of the
184 participants were male. The mean age of patients in the intervention group was 63 years (SD
185 = 15.8) and 60 years (SD = 15.2) in the control group. Haematological cancers were the most
186 commonly represented, followed by digestive cancers. The two groups were comparable in all
187 of these aspects.

188 **Table 1: Demographic and clinical characteristics of the study participants**

Characteristics	Intervention group (n=59)	Control group (n=30)	P-value
Age, years [mean (SD)]	63.0 (15.8)	60.0 (15.2)	0.28
Sexe [n (%)]			0.94
Male	31 (51.5)	16 (53.3)	
Female	28 (47.5)	14 (46.7)	
Type of cancer [n (%)]			0.19
Hematological	18 (30.5)	13 (43.3)	
Digestive	11 (36.7)	11 (36.7)	
Dermatological	13 (22.0)	2 (6.7)	
Urological	6 (10.2)	2 (6.7)	
Upper aerodigestive tract	4 (6.8)	2 (6.7)	

189

190 Knowledge and skills score

191 The mean score after 14 days was 8.97 (SD=3.85) for the control group and 12.66 (SD=2.57)
192 for the intervention group (p<0.001).

193 For each item, the percentage of patients who answered correctly increased in the intervention
194 group (Table 2). This percentage was significantly higher for eight questions, six of which
195 pertained to theoretical knowledge (items n°2,4,5,6,13 and17 about the usefulness of the
196 device, the length of time the device is worn, how to remove it, the role of the involved
197 parties, how to shower and bathe and the value of the traceability card), one related to know-
198 how (item n°10: who would you contact in complication cases?) and one to attitudes (item
199 n°11: how would you proceed to contact and alert?). In both groups, the item with the lowest
200 score was item n°8 about the four signs that indicate a complication or problem (27% vs 13%,
201 $p=0.14$). The item with the highest score was item n°9 (what would you do if these problems
202 occurred?) in the control group (86.7%) and item n°12 (do you know if you will have to pay
203 anything?) in the intervention group (93.2%).

204

Table 2: Correct answer rate for each item in the control and intervention groups

Item	Intervention group	Control group	P-value
	(n=59)	(n=30)	
	Number of correct answers (%)	Number of correct answers (%)	
1. Can you explain to me how your TIVAP is constituted? *	41 (69.5)	15 (50.0)	0.07
2. Tell me what is it for? *			
- What do we administer?	54 (91.5)	19 (63.3)	p<0.05
- Why do we need to administer it there?			
3. Who do you contact in an emergency? **	43 (72.9)	16 (53.3)	0.07
4. How long will you keep this device? *	47 (79.7)	18 (60.0)	p<0.05
5. Do you know how your TIVAP will be retired? *	43 (72.9)	13 (43.3)	p<0.05
6. Who are the different professionals who interact with your TIVAP? And what is their role? *	46 (78.0)	15 (50.0)	p<0.05
7. About the TIVAP maintenance, what do you know? What have you been told? *	44 (74.6)	20 (66.7)	0.43
8. What are the four signs that indicate a complication or problem? *	16 (27.1)	4 (13.3)	0.14
9. What would you do if these problems occurred? **			
- Dysfunction			
- Fever	54 (91.5)	26 (86.7)	0.73
- Inflammation			
- Opening of the scar			
10. Who would you contact in these cases? **	47 (79.7)	18 (60.0)	p<0.05
11. How would you proceed? *** (to contact and alert)	49 (83.1)	9 (30.0)	p<0.001
12. Do you know if you will have to pay anything? *	55 (93.2)	23 (76.7)	0.06
13. What have you been told about showering or bathing? *	27 (45.8)	7 (23.3)	p<0.05
14. Are there activities you think you can no longer do (activities to avoid)? *	36 (61.0)	13 (43.3)	0.11
15. If you are concerned that your care is not of good quality, who do you contact? **	30 (50.9)	10 (33.3)	0.12

16. If you were to explain this medical device to someone, what would you tell them? ***	35 (59.3)	12 (40.0)	0.08
17. What is the purpose of the traceability card you were given? *	29 (49.2)	7 (23.3)	p<0.05
18. How will you manage post-operative pain? ***	51 (86.4)	24 (80.0)	0.63

207 Legend: *=theoretical knowledge questions, **=know-how question, *** =attitude question
208

209 Discussion

210 Our study showed that pharmacist-led interviews were associated with significant differences
211 (statistically significant) in patient knowledge and skills related to TIVAP management, as
212 assessed through an 18-item questionnaire.

213 By presenting the outcomes one by one, a statistical progression was observed for eight out of
214 18 items, including six related to knowledge-based skills. The interviews therefore enable
215 patients to master the information related to the drugs administered, the duration of their
216 usage and the modalities used for removal of the TIVAP, as well as the medical device's
217 traceability. However, the interviews appear to have a lesser impact on skills related to
218 technical know-how and attitude. However, it should be noted that the control group already
219 displayed high scores in certain skills, such as knowing how to react in case of complications
220 (86.7%) or managing postoperative pain (80%). Although some safety skills, such as
221 recognizing the signs of complications or identifying activities to avoid, improved following
222 the intervention, the changes were not statistically significant. It is therefore reassuring to note
223 that the majority of skills are acquired after the intervention.

224 Pharmaceutical interviews have been shown to be effective in improving patient outcomes by
225 enhancing their knowledge, skills, and attitudes related to their health condition. Several
226 studies have examined the impact of pharmaceutical interviews on patient competences,
227 encompassing knowledge, know-how, and know-how to be. Overall, existing literature
228 suggests that conducting pharmaceutical interviews can significantly improve patient's
229 competences, resulting in improved medication adherence, decreased healthcare expenses,
230 and better health outcomes [20–27]. It has also been shown that the incorporation of
231 pharmacists into the multidisciplinary team on the ward improves patient safety and
232 satisfaction, and proves to be cost-effective when regularly provided throughout the stay [28].
233 Therefore, integrating a pharmacist into the care pathway of a cancer patient can include

234 educational interventions with patients wearing an implantable chamber, in addition to their
235 clinical pharmaceutical expertise.

236 Our study makes a unique contribution to the existing literature on patient's education by
237 focusing on the impact of pharmaceutical interviews on patients with a TIVAP. While
238 previous studies have explored the impact of educational interventions on medication
239 adherence and disease management, only a few have specifically addressed the management
240 of medical devices. The use of TIVAP is common among patients with cancer undergoing
241 chemotherapy, and the management of these devices can prove complicated and challenging.
242 Our study aims to fill a gap in the literature by examining how pharmaceutical interviews
243 affects patient proficiency related to TIVAP management, including knowledge of device use,
244 maintenance, and potential complications. The interview, which provided information on the
245 use of the device, its maintenance and potential complications, helped to improve patients'
246 understanding and self-management skills.

247 Some skills seem not to have been fully assimilated during the assessment. This may be due
248 to a lack of understanding or to receiving too much information simultaneously. Additionally,
249 it could be due to the patient's memory loss which may have occurred since the interview
250 took place 14 days ago. One solution could be offering the patient a document that
251 summarized all the points discussed and suggests the necessary course of action. Several
252 studies have shown that providing patients with a written document can improve their
253 knowledge on various medical issues. For example, Vanhaecke Collard *et al.* [29] showed
254 that elderly patients who were given a brochure had better knowledge and better adherence to
255 their treatments. Finally, a multifaceted educational approach is required to improve the
256 behavioral determinants of health [30]. In this regard, we have created a booklet, containing
257 all the necessary information for the patient to read at home. It would be interesting to
258 replicate this study on a third patient group that receives a multifaceted intervention

259 consisting of both the booklet delivery and the pharmaceutical interview. It would be
260 interesting to evaluate the impact of pharmaceutical interview on clinical outcomes,
261 particularly in the context of medical device management.

262 **Strengths and limitations**

263 Despite the positive impact of pharmaceutical interviews on patient competences, there are
264 still some limitations to consider. First, the monocentric nature of the study may limit the
265 general applicability of the findings to other settings, as well as the relatively small sample
266 size of included patients. Although efforts were made to include all eligible patients during
267 the study period, the generalizability of our results to a larger population may be impacted.
268 Additionally, the absence of randomization of patients to either the intervention or control
269 group poses a risk of selection bias. The fact that we did not calculate the sample size or
270 power required for the trial prior to its commencement adds to this concern. However, it is
271 important to note that while this study has strengths in that the baseline characteristics of the
272 intervention and control groups were comparable in terms of sex, age, and pathology, we are
273 aware that other elements could influence the score, such as level of education, occupation or
274 health literacy may have influenced the outcome. Furthermore, to the best of our knowledge,
275 no previous questionnaire or study has assessed patient knowledge and skills specifically
276 related to an implantable venous access port. This constitutes a valuable addition to the
277 current findings.

278 In terms of future studies, it should be noted that the present study reassessed patient
279 knowledge at 14 days after the pharmacy interview, which is a relatively short follow-up
280 period. It would be of interest to assess the durability of this knowledge over extended
281 periods. Finally, forthcoming research could investigate the long-term impact of pharmacist-
282 led interventions on patient clinical outcomes, or determine the most effective frequency and
283 duration of these interventions.

284 Conclusion

285 This study highlights the impact of pharmaceutical interviews on the knowledge and skills of
286 patients with TIVAP. Despite some limitations, our results provide a foundation for further
287 investigation into the potential benefits of these interventions. Future studies are needed to
288 explore the extended retention of knowledge several months after the interview, and the
289 impact on patient outcomes, including complication rate.

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298 *Nantais d’Ethique dans le Domaine de la Santé* (n°GNEDS20210609).

299 Author contributions:

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302 **Charlotte Grivel**: Conceptualization; Data curation; Roles/Writing - original draft; Writing -
303 review & editing

304 **Mathilde Petit**: Conceptualization; Data curation; Roles/Writing - original draft; Writing -
305 review & editing

306 **Pierre Chapron**: Conceptualization; Formal analysis; Roles/Writing - original draft; Writing
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309 **Erwan Corbiveau**: Conceptualization; Roles/Writing - original draft; Writing - review &
310 editing

311 **Romain Dumont**: Conceptualization; Roles/Writing - original draft; Writing - review &
312 editing

313 **Jean-François Huon:** Conceptualization; Formal analysis; Investigation; Methodology;
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315 review & editing

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402 **Figure 1: Consort flow diagram**