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Observational study of vaccination in cancer patients: how can vaccine coverage be improved?

Étude observationnelle sur la vaccination chez les patients atteints de cancer : comment améliorer la couverture vaccinale ?

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ABSTRACT

Background. Chemotherapy increases the risk of infections, often severe, and some of them are vaccine-preventable infections. We aimed to assess vaccination coverage and associated factors in oncology and hematology patients.

Methods. Consecutive adult patients followed in a French university hospital for hematological malignancy or solid cancer voluntarily completed an anonymous questionnaire in September and October 2016. It included questions on underlying disease, chemotherapy, flu, and pneumococcal vaccination uptakes, and attitudes toward vaccination. Factors associated with vaccination uptake were assessed by multivariate logistic regression.

Results. The response rate was 41.9% (n=671) among 1,600 questionnaires distributed; 232 patients had underlying hematological malignancy and 439 had solid cancer. Half of the patients were aged over 65 years. Chemotherapy was ongoing or discontinued for less than one year in 74.7% of patients. In patients aged <65 years undergoing chemotherapy, flu vaccination rate was 19.9% whereas patients aged >65 years had coverage of 47%. Pneumococcal vaccine uptake was 7.3%. However, 64.7% of patients were favorable to vaccination. Vaccine uptake was associated with age >65 years (OR 4.5 [2.9-7.0]), information about vaccination delivered by the family physician (OR 12.9 [5.5-30.1]), follow-up in hematology unit (OR 2.0 [1.3-3.1]), and positive opinion about vaccination (OR 2.0 [1.3-3.1]).

Conclusion. Despite specific recommendations regarding immunocompromised patients, anti-pneumococcal and flu vaccinations were rarely conducted, even in elderly patients. Targeted information campaigns to family physicians, oncologists, and patients should be implemented to improve vaccine coverage in patients with underlying malignancies.

RÉSUMÉ

Objectifs. L'objectif était d'estimer la couverture vaccinale et les facteurs associés chez des patients sous chimiothérapie suivis en oncologie et hématologie.

Méthodes. Tous les patients adultes consécutifs suivis pour hémopathie maligne ou cancer solide ont été sollicités pour répondre à un questionnaire (septembre et octobre 2016). Il comprenait des questions sur les comorbidités, la chimiothérapie, les vaccinations contre la grippe et antipneumococcique, et leurs attitudes vis-à-vis de la vaccination. Les facteurs associés à la vaccination ont été évalués par régression logistique multivariée.

Résultats. Le taux de réponse était de 41,9 % (1 600 questionnaires distribués) : 232 patients avec hémopathie maligne et 439 avec cancer solide. La moitié étaient âgés > 65 ans. Une chimiothérapie était en cours ou arrêtée depuis moins d'un an chez 74,7 % des patients. Chez les patients de < 65 ans, la couverture vaccinale contre la grippe était de 19,9 % contre 47 % chez ceux âgés de > 65 ans. La couverture vaccinale antipneumococcique était de 7,3 %. Cependant, 64,7 % des patients étaient favorables à la vaccination. Les facteurs associés à la vaccination étaient : âge > 65 ans (OR 4,5 [2,9-7,0]), informations sur la vaccination par le médecin généraliste (OR 12,9 [5,5-30,1]), suivi en service d'hématologie (OR 2,0 [1,3-3,1]) et opinion positive quant à la vaccination (OR 2,0 [1,3-3,1]).

Conclusion. Malgré les recommandations, la vaccination antipneumococcique et celle contre la grippe étaient rarement effectuées, même chez les personnes âgées. Des campagnes d'informations ciblant les médecins généralistes, oncologues et patients devraient être organisées.

INTRODUCTION

The World Health Organization (WHO) targets vaccination coverage rates for vaccinepreventable diseases ≥95% according to age. The only exception is for the influenza virus, for which the vaccination rate should reach 75% [1]. However, the WHO recommends antipneumococcal vaccine only for immunocompromised patients [2]. Patients presenting with cancer should benefit from vaccines as they are exposed to a heightened risk of invasive pneumococcal diseases (IPD) and influenza illness, leading to an increased risk of morbimortality [3-6]. In 2005 the overall incidence rate of IPD in adults with acquired immune deficiency, such as solid or hematological cancer, ranged from 300.4 to 503.1 cases/100,000 persons compared with 8.8 cases/100,000 persons in healthy adults [7]. A 2013 review confirmed that IPD risk in this population was 5 to 23 times higher than in the general population and that influenza illness was responsible for numerous complications [8]. Influenza-attributable mortality rate ranged between 11% and 33% in immunocompromised patients treated with chemotherapy compared with 10% in the general population [5]. Heavily immunosuppressed patients with solid cancer are at greater risk of developing pneumonia with subsequent high mortality [9]. The level of immunosuppression depends on the age, type of malignancy, and chemotherapy regimen [10]. Little data is available on immune deficiency persistence after the end of chemotherapy. Quantitative and qualitative T and B cell depletion continues months after chemotherapy administration. Therefore, French authorities implemented guidelines on vaccination for immunocompromised patients so as to reach the WHO objectives for vaccine coverage [11]. Diphtheria-tetanuspoliomyelitis (dTP) and anti-hepatitis B virus (HBV) vaccines are now recommended for use in the general population and vaccine boosters are specifically recommended three months after the end of chemotherapy in patients with solid cancer, and six months after chemotherapy in patients with hematological malignancy who undergo additional immunosuppressive chemotherapy. Anti-pneumococcal vaccination is based on a combined strategy: injection of 13-valent pneumococcal polysaccharide conjugate vaccine (PCV) followed at least two months later by 23-valent polysaccharide unconjugated vaccine (PPV). Although this vaccination has to be initiated preferably before the chemotherapy, it can be continued during treatment. Inactivated influenza vaccine is recommended during autumn at least two weeks before the predictable epidemic periods for all immunocompromised patients.

Vaccination remains a good strategy to decrease the infection risk and hospitalization rate [12]. In the PRISMA study, flu vaccination prevented 78% of deaths and 87% of hospitalizations for 1,778 high-risk patients aged over 65 years [13]. A recent review among immunosuppressed adults with cancer suggested lower mortality and better infection-related outcomes after influenza vaccination [14]. Since the introduction of pneumococcal vaccines, IPD incidence decreased from 20 to 8/100,000-population year between 2009 and 2014 in the immunocompromised population including patients undergoing chemotherapy for cancer, even with insufficient coverage [15]. However, in the general as well as the immunocompromised population, vaccination rates clearly fail to meet the goal set by the WHO, on which national goals are based [16,17]. For immunocompromised patients with autoimmune disease, solid organ transplantation, or hematological malignancy, vaccination rates against IPD and influenza are 49% and 59%, respectively [16]. Little data is presently available on vaccination coverage rate for patients with malignancies.

The aim of our study was to assess vaccination coverage and factors associated with appropriate vaccination in oncology and hematology patients.

METHODS

Study design and population

This monocentric observational study was constructed as a survey among patients with solid cancer or blood malignancy, followed in a French university hospital. Patients over 18 years were included when they came in consultation, as outpatients to the day hospital or in weekly hospitalization. Patients unable to answer to the questionnaire because of any incapacity and those coming for the first time for a diagnostic procedure were excluded from the study. Stem cell transplanted patients were also excluded because they have a specific vaccination follow up.

Data collection

Medical secretaries distributed a questionnaire to all those patients at the administrative registration in September and October 2016. After being informed, participants were asked to answer 16 multiple-choice questions for an overall estimated time of 5 minutes, alone and during their waiting time. The questionnaire was anonymous. Collected data was age,

sex, underlying malignancy, time to diagnosis, chemotherapy administration, pursuit or withdrawal of chemotherapy, opinions about vaccination, flu vaccinations of their relatives, previous vaccinations since diagnosis of cancer (without any precise date) against influenza, pneumococcus, HBV, and dTP. Another question concerned the most trustworthy person to deliver vaccination information and the need for more information on the subject. The main criterion of assessment was the number of patients who had been vaccinated since their cancer diagnosis. Physicians collected completed questionnaires.

Ethics

Participation in the survey was anonymous and voluntary. Since answering was voluntary, the study was not submitted to an ethics committee according to French policy. The French Data Protection Authority (French acronym CNIL), which is responsible for protection of individual data in France, approved the panel and its procedures. The study was declared in their database, with no need of approval request number.

Statistical analysis

Sample size calculations determined that 130 participants were needed per group for the primary endpoint. In anticipation of non-exploitable questionnaires at a rate of 5%, the sample size increased to 200 per group to ultimately analyze patients who had received chemotherapy and to compare patients in both groups.

Descriptive statistics were used to summarize all demographic and clinical characteristics of patients. Continuous variables were presented as mean and standard deviation (SD) or as median with range. Number and percentage were determined for categorical data. Variables with a *p*-value <0.25 in the univariate analysis were included for the multivariate analysis, after assessment of log-linearity. Bivariate interactions with a *p*-value <0.25 were included. Finally, odds ratio (OR) and their 95% confidence interval (95%CI) were estimated using a logistic regression multivariate analysis with a stepwise-descending selection procedure, removing first the interactions and then the variables with a *p*-value >0.05. The Hosmer-Lemeshow test confirmed the validity of the model. Susceptibility analysis with multiple imputations (n=5) was performed due to missing data.

RESULTS

Population characteristics

A total of 1,600 questionnaires were distributed (Figure 1). Among 671 (41.9%) respondents, the M/F sex ratio was 0.9 (Table 1). Half of the participants (336; 50.1%) were aged >65 years. They were divided into two groups: 232 (34.6%) were treated for hematological malignancy and 439 (65.4%) for solid cancer. A total of 501 patients (74.7%) received or had received chemotherapy. The main hematological malignancies included lymphoproliferative diseases, multiple myeloma, and acute leukemia. The three main localizations of solid cancers were the breast, digestive tract, and lung (Table 1).

Vaccination in the cancer population

Since cancer diagnosis 39.7% (n=267) of patients declared that they had received at least one vaccination: 148 in oncology and 119 in hematology (34.6% vs 52.9%, *p*-value <0.0001, respectively). To estimate the global adherence to vaccination, we analyzed the proportion of cancer patients vaccinated against a vaccine used in the general population (i.e., dTP) based on patients' declarations. The question of appropriate immunization regimen for HBV or pneumococcal prevention was not asked. dTP vaccination was up to date in 57.6% (n=387) of patients, similarly in both groups. Only 27.4% (n=184) were vaccinated against HBV, a non-mandatory vaccine, with similar rates in hematology and oncology patients. Reported pneumococcal vaccination rate was 7.2% (n=48): 5.1% in the oncology unit and 11.4% in the hematology unit (p=0.01). Flu vaccination had been performed in 28.6% (n=192) of patients, 47% (n=137) being aged over 65. The relatives of 173 patients (25.8%) were vaccinated against the flu (Table 2).

In the subgroup of 501 patients receiving chemotherapy, 40.5% (n=203) had been vaccinated since the cancer diagnosis, 19.9% (n=44) being aged <65 years. Pneumococcal and influenza vaccination rates were similar to that of the whole studied population, reaching 7.9% and 33.5%, respectively.

Vaccination perception of patients

A total of 423 patients (64.7%) had a good or very good opinion of vaccination as a whole. These patients were more vaccinated than those with a less favorable opinion (48.2% vs 33.7%; p<0.001). Family members of patients with a favorable opinion were also more vaccinated (38% vs 24%; p=0.005). Two thirds of the patients (66.6%) wished to improve their knowledge about vaccination. The most trustworthy person to deliver this information was considered to be the family physician for 36.2% of patients (n=166/458) or the oncologist for 56.8% (n=260/458).

Factors associated with vaccination

The results of the univariate and multivariate analyses are presented in Table 3. In the multivariate analysis, factors associated with a higher vaccination rate in the global population of the study were: age ≥ 65 years (OR 4.5 [2.9-7.0]; p<0.0001), information received from family physician (OR 12.9 [5.5-30.1]; p<0.0001), being treated for an hematological malignancy (OR 2.0 [1.3-3.1], p<0.008), and a positive opinion about vaccination (OR 2.0 [1.3-3.1]; p=0.003).

In the multivariate analysis, for the subgroup of patients receiving or having received chemotherapy, age \geq 65 years (OR 4.8 [3.0-8.0]; *p*<0.0001), information received from family physician (OR 11.6 [4.6-29]; *p*<0.0001), up-to-date dTP vaccination (OR 2.6 [1.5-4.3]; *p*=0.0003), and positive opinion about vaccination (OR 2.0 [1.2-3.3]; *p*=0.007) were associated with a higher rate of vaccination (Table 4).

DISCUSSION

Our study provides an overview of vaccination coverage in a population presenting with malignancy. Although clear guidelines about vaccination of immunocompromised patients already exist, only a limited number of studies about vaccination rates in this population is available. Our study reported that cancer patients are largely under-vaccinated against the main frequent and threatening diseases, namely IPD, pneumococcal pneumonia, and the flu.

With 7.9% and 33.5% of pneumococcal and flu vaccine coverage, respectively, the population of our study receiving chemotherapy is less vaccinated compared with previous literature reports. In the study by Loubet *et al.*, the vaccination rate was higher for pneumococcus (72%) and for the flu virus (39%) in patients receiving chemotherapy, albeit far from the WHO target, even in a biased population of people belonging to patients associations [16]. Other studies reported even lower rates from 25% to 30% for influenza

vaccines in immunocompromised patients with cancer [18,19]. In our study, vaccine uptake was nevertheless better for the flu than for pneumococcus. The French vaccine policy encourages flu vaccination in all patients aged over 65 years and in at-risk patients [20]. Every patient aged \geq 65 years receives a voucher from the public health insurance for free influenza vaccine irrespective of the underlying condition. This policy may explain the high rate of flu vaccine coverage in our study in the population aged \geq 65 years with cancer.

Various issues have arisen regarding HBV vaccination. The low rate of HBV vaccination (27.4%) might be partially due to the negative perception of HBV vaccination in France [21]. For young adults, immunocompromised or not, HBV vaccination coverage is insufficient with a rate of only 55.3% [22,23]. This vaccine is nonetheless recommended in cancer patients as in the general population, with the same objective of 95% vaccination rate. It has been demonstrated that acute infections in patients with cancer receiving chemotherapy are more likely to become chronic with rates around 18-26%, compared with 5-10% in adults over 50 years [24]. The mortality due to HBV is likewise higher in those patients than in the general population [24].

Our study underscored a low vaccination rate for cancer patients. There is not enough data on vaccine coverage in immunocompromised patients or in people with chronic conditions at increased risk of vaccine-preventable diseases. Available evidence suggests that this population is often under-vaccinated even in developed countries [24]. Two reasons may explain these low rates. First of all, vaccine immunogenicity in immunocompromised patients is questionable, as there is currently no consensus data on the period and the quality of the immune response on chemotherapy [18]. In a recent review, Vollaard *et al.* reported that the majority of patients with solid tumors were able to achieve a timely, protective immunological response regardless of the chemotherapy schedule, similar to healthy controls [25]. Further studies are however needed to address the issue of who should be vaccinated, with which other vaccines, with how many doses, and when during the chemotherapy. There is also a lack of vaccine knowledge leading to doubts about their adverse events and potential post-vaccine diseases [26], although there is no such risk if recommendations are followed. Moreover, the influence of the anti-vaccine lobbies remains present in France [27], notwithstanding a real decrease in morbidity and mortality in cancer population due to vaccination [13,15,28]. However, two thirds of our patients wished to improve their knowledge about vaccination, and the same proportion had a good opinion about vaccination.

Our study also suggested reasons for the lack of vaccine uptake and how to improve vaccination coverage in the cancer population. The most significant factor associated with vaccination consists in the information delivered by the family physician. Even with oncologists as the most trustworthy persons according to patients, there was no significant association with vaccination. One could hypothesize that in our study oncologists are not the persons who usually deliver vaccine information or prescription. Despite available national guidelines, family physicians and specialists are not sufficiently informed about vaccine recommendations [18]. Involving family physicians directly by means of oncologists could help improve vaccination coverage. Furthermore, favorable opinions about vaccination were linked to higher vaccination rates. This factor was previously demonstrated for the flu and pneumococcal vaccines in immunocompromised patients [29,30]. To conclude, given the current vaccination controversies, more pedagogy about vaccine efficacy and safety is clearly needed.

There are several limitations to our study. All patients did not return the questionnaire, leading to a selection bias. We did not have access to socio-demographic data of non-responders, which could have ruled out the presence of a selection bias, by comparison with responders' data. However, we had a good rate of response, exceeding 40%, when 15-20% are needed in a survey [31]. The other possible confounding factor could stem from the fact that it was impossible to individually check each patient's vaccine status and time of vaccine uptake. Our data was only declarative as we performed a monocentric study with no use of medical records. Although serological results would have helped us to identify vaccinated patients, patients' answers to the survey questionnaire was only used. A questionnaire administered to the medical team would have given complementary information.

The questionnaire did not ask for precise vaccination timing since the diagnosis of cancer. Thus, dTP vaccination rather reflects the global vaccine status than the vaccine status since cancer diagnosis. Therefore, dTP vaccination appears as an independent factor associated with vaccination (OR 2.6 [1.5-4.3]; p=0.0003). However, the study shows that vaccine coverage in cancer patients remains globally insufficient for pneumococcus and the flu.

Conclusion

Cancer patients – even elderly ones – are rarely vaccinated despite specific recommendations. Ways to improve the vaccination coverage in onco-hematology patients are: (i) targeted information campaigns directed at patients and physicians about the efficacy, safety, and benefits of vaccines, (ii) information given to and/or training of family physicians, (iii) reinforcement of links between family physicians and oncologists.

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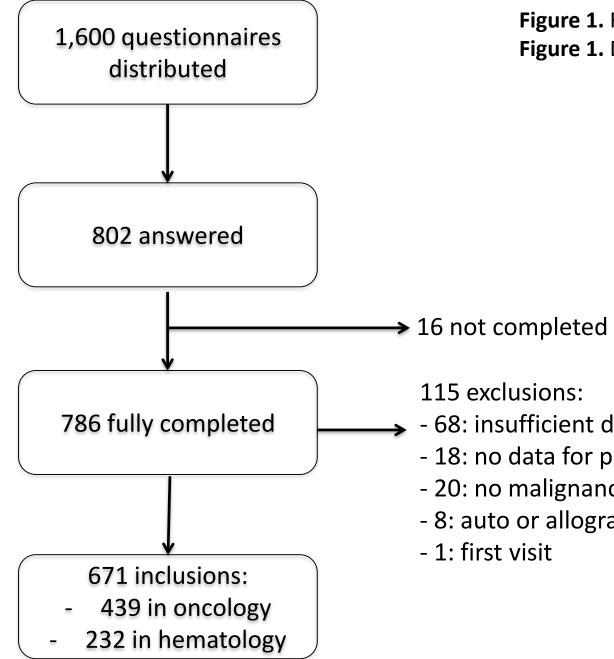


Figure 1. Flowchart of the study Figure 1. Diagramme de flux de l'étude

- 68: insufficient demographic data
- 18: no data for primary endpoint
- 20: no malignancy
- 8: auto or allograft

Table 1. Characteristics of patients

Tableau 1. Caractéristiques des patients

Hematology n (%)	Total
n (%)	
11 (70)	n (%)
232 (34.6)	671
134 (57.8)	336 (50.1)
132 (56.9)	320 (47.7)
36,5 (0-365)	22 (0-365)
163 (70.3)	501(74.7)
102 (44.0)	369 (55.0)
-	-
-	-
-	-
	-
-	-
-	-
-	-
-	-
131 (56.0)	-
34 (15.0)	-
15 (6.0)	-
34 (15.0)	-
18 (8.0)	-
	232 (34.6) 134 (57.8) 132 (56.9) 36,5 (0-365) 163 (70.3) 102 (44.0) 102 (44.0) 131 (56.0) 14 (15.0) 15 (6.0) 15 (6.0) 15 (6.0)

Table 2. Vaccines received by the study population**Tableau 2.** Vaccins reçus par la population à l'étude

Total population	Oncology	Hematology	Total	
	(n=439)	(n=232)	(N=671)	<i>p</i> value
Patients vaccinated since cancer diagnosis	148 (33.7)	119 (51.2)	267 (39.7)	<.0001
dTP vaccination				
- Within the last 10 years	245 (55.8)	142 (61.2)	387 (57.6)	0.17
- More than 10 years before	133 (30.2)	66 (28.5)	199 (29.7)	0.61
HBV vaccination	123 (28.0)	61 (26.3)	184 (27.4)	0.63
Pneumococcal vaccination	22 (5.1)	26 (11.2)	48 (7.2)	0.01
Flu vaccination	117 (26.7)	75 (32.3)	192 (28.6)	0.12
Flu vaccination of family members	98 (22.3)	76 (32.7)	173 (25.8)	0.003

Table 3. Univariate and multivariate analyses of factors associated with vaccination in the global population of cancer patients

Tableau 3. Analyses univariée et multivariée des facteurs associés à la vaccination dans la population globale de patients atteints de cancer

	Univariate	Multivariate analysis	
Factors	analysis (p value)	OR [IC95%]	<i>p</i> value
Age	<.0001		<.0001
<65 years		1	
≥65 years		4.5 [2.9-7.0]	
Gender	.40		
dTP	.004		
<10 years		2.1 [1.3-3.4]	
≥10 years		1	
HBV vaccination	.82		
Information given by family physician	<.001		<.0001
No			
Yes		12.9 [5.5-30.1]	
Information given by cancer specialist	<.001		
Oncology	<.001	1	.008
Hematology		2.0 [1.3-3.1]	
Positive opinion about vaccination	.0002		.003
No		1	
Yes		2.0 [1.3-3.1]	

Table 4. Univariate and multivariate analyses of factors associated with vaccination in the subset of cancer patients receiving or having received chemotherapy

Tableau 4. Analyses univariée et multivariée des facteurs associés à la vaccination dans le sous-groupe de patients atteints de cancer sous chimiothérapie ou ayant été sous chimiothérapie

	Univariate	Multivariate analysis	
-	analysis (p value)	OR [IC95%]	p value
Age	<.0001		<.0001
<65 years		1	
≥65 years		4.8 [3.0-8.0]	
Gender	.73		
dTP	.02		.0003
<10 years		2.6 [1.5-4.3]	
≥10 years		1	
HBV vaccination	.69		
Information giver by family physician	<.001		<.0001
No		1	
Yes		11.6 [4.6-29.0]	
Information given by oncologist	<.001		
Oncology	<.001		
Hematology Positive opinion about vaccination	.009		.007
No		1	
Yes		2.0 [1.2-3.3]	