

Patients with anal cancer: a French Hospital database analysis

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1 CONTEXT

INCYTE wishes to retrieve information on patients treated with one of the anti-PD1 antibody and with an anal cancer through the analysis of PMSI hospitalization database.

Anti-PD1 antibody are however used without a marketing authorisation in anal cancer treatment in second line after platinum-based chemotherapy. Incyte wishes to know the number of patients treated for this indication with either one of these drugs.

CEMKA has extensive experience in the analysis of claim databases in France. This experience has been gained through the exploitation of these databases as they evolve both for public health authorities and for private actors. CEMKA has also been conducting observational studies for more than 20 years.

CEMKA proposed INCYTE to perform an analysis of the French Hospital database (PMSI). This document presents the approach and the results of analysis.

2 OBJECTIVES

The objective of this study is to identify cancer anal patients treated with PD1/PDL1 in second line after platinum-based chemotherapy and to describe their treatment pattern.

3 METHOD

3.1 Type of study

This is a retrospective cohort study of all adult cancer anal patients (aged 18 years or older) identified in the PMSI database.

The following hypothesis have been made to identify patients:

1. Identification of adult patients with anal cancer in hospital database 2019 and treated with a PD1/PDL1 ("initial stay"):
 - all patients with a diagnosis of C21 (ICD-10 code) "Malignant neoplasms of anus and anal canal » (main, related or associated diagnosis) AND a PD1/PDL1 treatment were selected
 - PD1/PDL1 treatment:
 - IMFINZI®: durvalumab (L01XC28)
 - OPDIVO®: nivolumab (L01XC17)
 - TECENTRIQ®: atezolizumab (L01XC32)
 - KEYTRUDA®: pembrolizumab (L01XC18)
 - BAVENCIO®: avelumab (L01XC31)
 - LIBTAYO®: cemiplimab (L01XC33)
2. Identification of the treatment pattern in the two previous years for each patient: 2017 and 2018
 - PD1/PDL1 treatment previously received.
 - Other cancers identified for the patients except secondary cancers (metastasis) according to the following ICD-10 codes diagnosis:
 - C77: Secondary and unspecified malignant neoplasm of lymph nodes

- C78: Secondary malignant neoplasm of respiratory and digestive organs
 - C79: Secondary malignant neoplasm of other and unspecified sites
3. Study period: 2017-2019 (Identification of anal cancer and PD1/PDL1 in 2019 and identification of treatment pattern in 2017 and 2018)
 4. French Hospital database used: French hospital MSO (Medecine Surgery Obstetric)

3.2 Access of PMSI database

As part of the law on the modernization of the national health system and in particular in accordance with Article 193 on the provision of health data, the Technical Agency for Information on Hospitalization (ATIH) set out new modalities of access to the PMSI databases.

The databases are always purchased from the ATIH but access to the data has been made since 31/01/2016 from the CASD Data Center (Secure Data Access Center). This means that CEMKA no longer has the "physically" base in-house and is accessible "remotely" on the CASD servers.

In addition, to facilitate access to PMSI data, a reference methodology (MR-006), relating to access by consulting firms or research laboratories on behalf of healthcare companies, was approved by the CNIL on 7 June 2018 and sent to the French Official Journal for publication (published 13 July 2018).

For treatments eligible to the MR-006 law, responsible of treatment, sponsors of the study should:

- Before their implementation, proceed to their commitment of compliance with the CNIL (<https://www.cnil.fr/fr/declarer-un-fichier> / choose « Effectuer un engagement de conformité ». In return, the CNIL will automatically send a receipt with the commitment number). This is only to be done once.

- To record each of their treatments on the public directory of the studies carried out under MR managed by the INDS (<https://www.indsante.fr/fr/repertoire-public-des-etudes-realisees-sous-mr>)

If the responsible of the treatment is not an institution, it should sign an agreement with the ATIH which identify the consultancy performing analyses.

The consultancy should sign a consultancy with ATIH.

CEMKA has already an access to the CASD platform which allows the access of PMSI databases.

The PMSI database access, on the secure CASD platform, was available in November 2020.

3.3 The French Hospital Database

The PMSI database is a comprehensive and quasi exhaustive database on hospital stays in France.

The PMSI database contains all hospital stays for one year in private and public medical establishments (about 30 millions of stays).

The main available variables are: identification of medical establishment, gender and age of patient, if the patient is dead, all diagnosis (ICD X of the WHO), the length of stay including the length in an intensive care unit, all medical procedures (CCAM classifications), where the patient comes from and where he will be discharge (at home or in other medical unit).

It is then possible to link the PMSI database with the National Hospital database FINESSE to get the information relative to hospitals.

Medications and medical devices consumption that are registered on a specific formulary named "additional list of drugs" are also available. The reason is that hospitals could charge the Sickness Funds on top of the DRG for these products.

Today, the databases are available from 2010 now on 2019.

The following information is available for each stay.

Table 1 : Variables of the French PMSI database

Data Element	PMSI
ICD X : primary and secondary diagnoses	X
Procedures codes (CCAM)	X
Hospital (name)	X
Type of hospital (private, public, teaching status, general hospital by group of number of beds)	X
Patient age	X
Gender	X
DRG	X
LOS (including day care hospital, less than 48 hours)	X
Patient origin (home, other hospital...)	X
Patient disposition (rehab, skilled nursing ...)	X

4 RESULTS

4.1 Number of patients

On the French Hospital database 2019, 153 stays have been identified with a diagnosis of anal cancer (ICD-10 C21) and a treatment with a PD1/PDL1 as following:

- C21 "Malignant neoplasms of anus and anal canal »
- PD1/PDL1 treatment :
 - IMFINZI®: durvalumab (L01XC28)
 - OPDIVO®: nivolumab (L01XC17)
 - TECENTRIQ®: atezolizumab (L01XC32)
 - KEYTRUDA®: pembrolizumab (L01XC18)
 - BAVENCIO®: avelumab (L01XC31)
 - LIBTAYO®: cemiplimab (L01XC33)

This tables precise the UCD code for each drug.

UCD13	UCD7	Médicaments
3400894307365	9430736	BAVENCIO 200 MG SOL INJ PERF
3400894243229	9424322	AVELUMAB 200 MG SOL INJ PERF
3400894379393	9437939	DURVALUMAB ASZ 50MG/ML INJ FL 2.4ML
3400894405511	9440551	IMFINZI 120 MG SOL INJ FL 2.4ML
3400894405450	9440545	IMFINZI 500 MG SOL INJ FL 10ML
3400894197232	9419723	KEYTRUDA 100 MG SOL INJ PERF FL
3400894095354	9409535	KEYTRUDA 50 MG SOL INJ PERF FL
3400894474708	9447470	LIBTAYO 350 mg sol diluer p perf
3400894094524	9409452	OPDIVO 100 MG SOL INJ FL
3400894389798	9438979	OPDIVO 10MG/ML PERF FL24ML
3400894094692	9409469	OPDIVO 40 MG SOL INJ FL
3400894514312	9451431	ATEZOLIZUMAB 840 mg sol diluer p perf [ATUc]
3400894312628	9431262	TECENTRIQ 1200MG SOL INJ FL
3400890002257	9000225	TECENTRIQ 840MG PERF FL14ML

These 153 stays correspond to 32 patients (a patient may have more than one stay in 2019).

Among them:

- 27 patients received the PD1/PDL1 treatment in 2019 only;
- 4 patients received the PD1/PDL1 treatment in 2018 and 2019;
- 1 patient received the PD1/PDL1 treatment in 2017 and 2018 and 2019.

In summary, 5 patients have already received PD1/PDL1 treatment in 2017 and 2018.

4.2 Treatment pattern

The treatment pattern of each patient was described using the two hospital databases 2017 and 2018.

Among the 32 patients identified with anal cancer and PD1/PDL1 treatment:

- 11 patients have only an anal cancer (ICD-10 C21 without any other ICD-10 codes for another cancer);
- 21 patients have other cancers (other than secondary cancers) coded in other hospital stays in the 2017 and 2018 database.

The following table presents all combination of all cancers (except secondary cancers) for these 21 patients:

Combination of other cancers (N=21 patients)	N	%
C20 (Malignant neoplasm of rectum)	4	19.05
C435 (Malignant melanoma of trunk)	3	14.29
C439 (Malignant melanoma of skin, unspecified)	2	9.52
C161 (Malignant neoplasm of fundus of stomach)/C20 (Malignant neoplasm of rectum)	1	4.76
C187 (Malignant neoplasm of sigmoid colon)/C19 (Malignant neoplasm of rectosigmoid junction)/C20 (Malignant neoplasm of rectum)/C758 (Malignant neoplasm with pluriglandular involvement, unspecified)/C817 (Other Hodgkin lymphoma)	1	4.76

C19 (Malignant neoplasm of rectosigmoid junction)	1	4.76
C20 (Malignant neoplasm of rectum)/C435 (Malignant melanoma of trunk /C439 (Malignant melanoma of skin, unspecified)	1	4.76
C20 (Malignant neoplasm of rectum)/C438	1	4.76
C20 (Malignant neoplasm of rectum)/C439 (Malignant melanoma of skin, unspecified)	1	4.76
C20 (Malignant neoplasm of rectum)/ C672 (Malignant neoplasm of lateral wall of bladder)	1	4.76
C341 (Malignant neoplasm of upper lobe, bronchus or lung)/C349 (Malignant neoplasm of unspecified part of bronchus or lung)	1	4.76
C437 (Malignant melanoma of lower limb, including hip)	1	4.76
C439 (Malignant melanoma of skin, unspecified)/C449(Other and unspecified malignant neoplasm of skin, unspecified)/C460 (Kaposi's sarcoma of skin)/C713 (Malignant neoplasm of parietal lobe)	1	4.76
C445 (Other and unspecified malignant neoplasm of skin of trunk)	1	4.76
C740 (Malignant neoplasm of cortex of adrenal gland)/C800 (Disseminated malignant neoplasm, unspecified)	1	4.76
TOTAL	21	100%

Considering the 3 years of hospital database for each patient, we identified pre-stay treatments coded as anal cancer and PD/PDL1:

- 18 patients (56.25%) received a chemotherapy treatment (coded with the ICD10 diagnosis code Z511"Encounter for antineoplastic chemotherapy and immunotherapy" or a DRG 28Z07Z "chemotherapy")
- 9 patients (28,13%) received a radiotherapy treatment (coded with the ICD10 diagnosis code Z510 "Encounter for antineoplastic radiation therapy »)
- 13 patients (40,63%) had surgery

Overall, 25 patients (78,13%) received another treatment before the stay in 2019, during which the anal cancer and a PD1/PDL1 were identified ("initial stay").

The following table presents combinations of all treatments received before the initial stay. The first line of this table identifies 7 patients without any treatment (no chemotherapy, no radiotherapy and no surgery).

Chemotherapy	Radiotherapy	Surgery	N	%
0	0	0	7	21.88
0	0	1	5	15.63
0	1	0	1	3.13
0	1	1	1	3.13
1	0	0	8	25.00
1	0	1	3	9.38
1	1	0	3	9.38
1	1	1	4	12.50
Total patients			32	100.00

The table presents the type of surgery for the 13 patients.

	French DRG term	Translation	N	%
06C031	Résections rectales, niveau 1	Rectal resection	1	7.69
06C043	Interventions majeures sur l'intestin grêle et le côlon, niveau 3	surgery on small intestine	3	23.08
06C141/ 11C131	Interventions sur le rectum et l'anus autres que les résections rectales, niveau 1/ Interventions par voie transurétrale ou transcutanée pour des affections non lithiasiques, niveau 1	Surgery on rectum/anus other than resection / Transurethral or transcutaneous interventions for non-lithiasic conditions	1	7.69
06C144	Interventions sur le rectum et l'anus autres que les résections rectales, niveau 4	Surgery on rectum/anus other than resection	1	7.69
06C14J	Interventions sur le rectum et l'anus autres que les résections rectales, en ambulatoire	Surgery on rectum/anus other than resection in ambulatory care	1	7.69

06C19J	Hémorroïdectomies, en ambulatoire	Hemorrhoidectomies	1	7.69
08C58J	Arthroscopies de l'épaule, en ambulatoire	Arthroscopies of the shoulder	1	7.69
10C031	Interventions sur les glandes surrénales, niveau 1	Surgery on the adrenal glands	1	7.69
11C131/ 16C032/ 17C063	Interventions par voie transurétrale ou transcutanée pour des affections non lithiasiques, niveau 1/ Autres interventions pour affections du sang et des organes hématopoïétiques, niveau 2/Interventions majeures de la CMD17, niveau 3	transurethral or transcutaneous interventions for non-lithiasic conditions / Other interventions for diseases of the blood and hematopoietic organs	1	7.69
11C132	Interventions par voie transurétrale ou transcutanée pour des affections non lithiasiques, niveau 2	transurethral or transcutaneous interventions for non-lithiasic conditions	1	7.69
11C133	Interventions par voie transurétrale ou transcutanée pour des affections non lithiasiques, niveau 3	transurethral or transcutaneous interventions for non-lithiasic conditions	1	7.69

A individual file was done with the 32 patients and the following data:

- # patient (1 to 32)
- All date of stay before the initial stay and the ICD10 code diagnosis coded into 3 categories: Melanoma, Rectum, Other cancer
- If PD1/PDL1 treatment was used during a stay, the cell has been highlighted in green

4.3 Summary

32 patients were identified in the French Hospital database 2019 with anal cancer and PD1/PDL1 treatment of whom 27 received the PD1/PDL1 treatment in 2019 only and 5 patients have already received PD1/PDL1 treatment in the 2-past year (2017 and 2018) ;

- 11 patients have only a anal cancer (ICD-10 C21) so we are sure that the PD1/PDL1 treatment was delivered for the anal cancer;
- 21 patients have other cancers (coded before the stay with anal cancer) so we are not sure for with cancer the PD1/PDL1 treatment was delivered.

On the 32 patients:

- 7 patients received no other treatment before the initial stay (no chemotherapy, no radiotherapy).
- 25 patients received other treatment before the initial stay of whom 20 patients received chemotherapy or radiotherapy (+/- surgery) and 5 patients had a surgery (only).