The impact of oncological package implementation on the treatment of rectal cancer in years 2013-2019 in Poland – multicenter study

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Abstract

Purpose: In 2015, in Poland, the oncological package (OP) was established. This law constituted a fast track of oncological diagnosis and treatment and obligatory multidisciplinary team meetings (MDT). The aim of this study was to analyze the impact of OP on rectal cancer treatment.

Methods: The study was a multicenter, retrospective analysis of data collected from five centers. It included clinical data of patients operated due to rectal cancer between 2013-2019. For most analyses, patients were categorized into three groups: 2013-2014 – before OP (A), 2015-2016- early development of OP (B), 2017-2019 – further OP functioning (C).

Results: A total of 1418 patients were included. In all time intervals, the majority of operations performed were anterior resections. There was a significantly lower local tumor stage (T) observed in subsequent time intervals, while there were no significant differences for N and M. In period C median of resected nodes was significantly higher than in previous periods. Four of the centers showed an increasing tendency in the use of preoperative radiotherapy. The study indicated a significant increase in the use of short-course radiotherapy (SCRT) and a decrease in the number of patients who did not receive any form of preoperative therapy in subsequent periods. In the group that should receive radiotherapy (T3/4 or N+ and M0), the use of SCRT was also significantly increasing.
Conclusion: In the whole cohort, there was a significant increase in the use of preoperative radiotherapy and decrease in T stage, changing with the development of OP. Nevertheless, this relation is indirect and more data should be gathered for further conclusions.

Trial registration number at ClinicalTrials.gov: NCT04947020

Date of registration: 24th of June 2021

1. Introduction

Cancer is one of the major problems of healthcare systems in developed countries. Currently it stands as the second cause of death in EU [1] with projections that its incidence and number of cancer-related deaths will increase [2, 3].

Cancer treatment and diagnosis is a very demanding and cost-generating process. The outcomes of cancer treatment are diverse among the countries but also between centers in one country [4, 5]. This is not only the result of equipment quality, access to newly developed therapies, or expenditures but treatment outcomes depend a lot on the healthcare system organization. Several measures have since been established to optimize the standardization of diagnosis and treatment of cancer patients, including time limitations for diagnosis and treatment initiation, and reporting of quality indicators like complication rate, survival, or operative specimen quality assessment. In Poland, in 2015 a new regulation of cancer care was introduced called Oncological Package (OP). Although the oncological package is not mandatory for all cancer patients or care providers, meeting the OP prerequisites entitles the hospital to a higher refund from the National Health Fund

OP included innovations such as limited time for initial diagnosis and clinical staging, treatment initiation within maximum of 7 weeks, and obligatory multidisciplinary team meetings (MDT) [6]. The multidisciplinary team includes a surgeon, medical oncologist, radiotherapy specialist, and treatment coordinator, responsible for scheduling all necessary diagnostic and therapeutic procedures.

To assess the results of such programs usually several more common neoplasms are analyzed in terms of treatment quality and long-term results. Rectal cancer is one of the more common tumors in both sexes and it may require surgery, radiotherapy, and chemotherapy in different sequences [4, 7–9]. Despite a significant improvement in rectal cancer treatment and outcomes in recent years [10, 11], the standards of treatment are still diverse and not always in accordance with the guidelines. Therefore, better organization and coordination of healthcare should result in more standardized management.

The aim the study was to find out whether implementation of new regulation of cancer management – OP into clinical practice have influenced the application of different treatment methods, staging of rectal cancer at the time of operation and patients' outcomes.

2. Methodology

The study was a multicenter, retrospective study based on hospital databases. The study acronym is BARO-1 (dataBase for Analysis of Rectal cancer Oncological results), registration number at ClinicalTrials.gov is: NCT04947020.

Patients from five tertiary centers in Poland treated within the period 2013–2019 were included. All patients over the age of 18 years with primary rectal cancer (up to 15cm from the anal verge) were included except for recurrent rectal cancer or patients for radicalization after local cancer excision.

The following data was included in the MS Excel database: type of neoadjuvant treatment (if any), time-interval between the end of neoadjuvant treatment and surgery, type of surgery, staging of rectal cancer based on pathological examination (pTNM), number of retrieved lymph nodes and metastatic lymph nodes, “R” classification (radicality of surgery), and date of death or last follow-up.

Statistical analysis was performed using SPSS software (version 28.0.1.0). Abnormal distribution was assumed for all groups. T-student, U-Mann-Whitney, and Kruskal-Wallis tests were used in the study. The study was approved by the Bioethics Committee of Jagiellonian University in Krakow, Poland (number of approval: 1072.6120.120.2021).

3. Results

1418 patients were included in the analysis. 5 patients had incomplete data pertaining radiotherapy, so they were excluded from the analysis. Patients were divided into three groups depending on the date of operation. The first group included patients treated prior to OP implementation – 2013-2014 (period defined “A”). In the second were patients operated between 2015-2016 (B) during the time of OP implementation and its early development. The last group consisted of patients operated in the period 2017-2019 (C) when OP became routine practice.

Patients were treated in five different tertiary centers. Three of them (1,2,4) were high-volume (minimum 50 cases per year) while another two (3,5) were low-volume (<50 cases per year) (Tab. 1). Center No. 4 was oncological, which means the institution managed cancer patients only and had chemotherapy and radiotherapy facilities on-site. Other centers (No. 1, 2, 3, 5) were tertiary hospitals where radiotherapy or chemotherapy was administered to patients by another hospital upon formal agreement.

Table 1. Number of patients operated in different centers.

	1	2	3	4	5	all centers
2013-2014	163	113	11	170	15	472
2015-2016	147	79	6	96	15	343
2017-2019	174	100	29	235	60	598
all years	484	292	46	501	90	1413

3.1 Patients characteristics

The median age of the whole group was 67 (68, 67, 67 in A, B, and C periods respectively). In all periods there was a predominance of males, with no statistical differences. The number of tumors localized in 0-5cm from the anal sphincter was significantly higher with time, while the percent in 6-10 cm was lowering. The most common types of surgery in all intervals were respectively: anterior resection, abdomino-perineal resection, and Hartman procedure (Table 2).

In patients without metastases (M0), with tumors localized 0-5cm from the anal sphincter there was a significant decrease in the percent of procedures with a stoma (72.93%, 65.63%, and 59.43% in periods A, B, and C respectively; p = 0.048).

Table 2. Demographics, prevalence of tumor localization, and type of operation.

		all		2013-2014		2015-2016		2017-2019		p chi2			
		n	%	N	%	n	%	n	%	ABC	A vs B	A vs C	B vs C
	number of patients	1413		473		343		598					
age	median	67		68		67		67		0.062	0.163	0.019	0.543
	range	29-95		29-92		31-95		30-95					
sex	male	909	64.33%	297	62.79%	226	65.89%	386	64.55%	0.676	0.383	0.583	0.678
	female	504	35.67%	175	37.00%	117	34.11%	212	35.45%				
tumor localization	0-5 cm	494	34.96%	158	33.40%	121	35.28%	215	35.95%	0.037	0.799	0.018	0.056
	6-10 cm	472	33.40%	182	38.48%	128	37.32%	162	27.09%	0.015	0.483	0.005	0.059
	>10 cm	219	15.50%	72	15.22%	59	17.20%	88	14.72%	0.806	0.563	0.579	0.936
type of operation	anterior resection	811	57.40%	274	57.93%	197	57.43%	340	56.86%	0.936	0.898	0.718	0.846
	Hartman procedure	177	12.53%	67	14.16%	37	10.79%	73	12.21%	0.34	0.154	0.344	0.518
	abdomianl perineal resection	302	21.37%	96	20.30%	70	20.41%	136	22.74%	0,557	0.964	0,336	0.410
	local resection	45	3.18%	6	1.27%	21	6.12%	18	3.01%	<0,001	0.001	0,056	0.021
	other	76	5.38%	29	6.13%	17	4.96%	30	5.02%	0,67	0.474	0,426	0.971

3.2 Histopathological outcomes

Histopathological outcomes were compared among time interval groups. The number of patients with stage pT2 or pT3 significantly decreased with time while the diagnosis of pT1 was significantly increasing. Features pT0 or pTis were more common in B and C periods than in A. There were no significant differences in pN and M features. Tumor staging also did not change significantly between analyzed periods.

The median number of resected nodes was significantly higher in period C than in periods A and B. In the whole cohort, the R0 radicality of resection was 79.49%, 75.58%, and 80.37% in periods A, B, and C respectively. The difference between periods B and C was statistically significant.

In the group of patients without metastases (M0; n=1136) the percent of patients in which R0 was achieved was 94.10%, 92.94%, and 94.13% respectively in periods A, B, and C, but differences were not statistically significant (Tab. 3).

Table 3. Staging and number of lymph nodes (harvested and metastatic).

		all		2013-2014		2015-2016		2017-2019		p chi2			
		n	%	n	%	n	%	N	%	ABC	A vs B	A vs C	B vs C
	number of patients	1418	100%	473	33.36%	344	24.26%	601	42.38%				
	pT0 or pTis	74	5.22%	12	2.54%	25	7.27%	37	6.16%	0.005	0.002	0.006	0.513
	pT1	77	5.43%	16	3.38%	17	4.94%	44	7.32%	0.019	0.291	0.006	0.148
	pT2 or pT3	1077	75.95%	383	80.97%	262	76.16%	432	71.88%	<0.001	0.010	<0.001	0.136
	pT4	105	7.40%	28	5.92%	22	6.40%	55	9.15%	0.106	0.838	0.059	0.132
	pN0	798	56.28%	252	53.28%	197	57.27%	349	58.07%	0.331	0.216	0.189	0.912
	pN+	521	36.74%	185	39.11%	120	34.88%	216	35.94%				
	M0	1167	82.30%	395	83.51%	280	81.40%	492	81.86%	0.261	0.125	0.189	0.691
	M+	186	13.12%	52	10.99%	51	14,83%	83	13,81%				
	R0	1119	78.91%	376	79.49%	260	75,58%	483	80,37%	0,114	0,111	0,734	0,046
Resected Nodes	median	11	n=1289	10	n=433	10	n=303	12	n=553	<0,001	0,912	<0,001	<0,001
	Range	0-77		0-34		0-35		0-77					
Positive nodes	median	0	n=1283	0	n=432	0	n=302	0	n=549	0,458	0,354	0,241	0,939
	range	0-46		0-21		0-20		0-46					
Stage	number of patients	1323		440	33.26%	320	24,19%	563	42,55%				
	0	69	5.22%	12	2.73%	22	6,88%	35	6,22%	0,015	0,006	0,009	0,702
	1	309	23.36%	99	22.50%	78	24,38%	132	23,45%	0,832	0,546	0,724	0,755
	2	367	27.74%	129	29.32%	83	25,94%	155	27,53%	0,583	0,305	0,533	0,608
	3	396	29.93%	149	33.86%	87	27,19%	160	28,42%	0,082	0,05	0,064	0,695
	4	182	13.76%	51	11.59%	50	15,63%	81	14,39%	0,238	0,106	0,194	0,619

3.3 Use of radiotherapy

The analysis of the application of different types of radiotherapy indicated that in four of the centers (1,2,3,4), both oncological and non-oncological, the percent of patients treated with preoperative radiotherapy (short-course radiotherapy (SCRT) or radiochemotherapy (RCT)) was increasing while in one (5), a non-oncological, low-volume center, it was decreasing (Fig. 1). The use of radiotherapy was highest in center 4 (81.64% in the whole analyzed period), the oncological center. In the other non-oncological centers, the percent of patients receiving radiotherapy ranged between 27.78% - 49.79%. The lowest use was reported in the two low-volume, non-oncological centers (No. 3 and 5), which enrolled the lowest number of patients for this trial, potentially influencing the result.

When comparing the percent of patients treated with different forms of radiotherapy among analyzed periods, there was a significantly higher use of SCRT and any form of preoperative radiotherapy (SCRT or RCT) in period C than in both periods A and B. In the same period, there was a significant decrease in percent of patients not receiving any form of radiotherapy. The use of postoperative radiotherapy did not differ significantly (Tab. 4).

Table 4. Application of different types of radiotherapy therapy.

	all		2013-2014		2015-2016		2017-2019		p chi2	A vs B	A vs C	B vs C
	n	%	n	%	n	%	n	%				
number of patients	1413	100%	472	33.40%	343	24.27%	598	42.32%				
SCRT	612	43.31%	195	41.31%	128	37.32%	289	48.33%	0.003	0.25	0.022	0.001
RCT	199	14.08%	57	12.08%	58	16.91%	84	14.05%	0.147	0.05	0.344	0.238
any preoperative radiotherapy	811	57.40%	252	53.39%	186	54.23%	373	62.37%	0.005	0.813	0.003	0.014
postoperative radiotherapy	55	3.89%	23	4.87%	14	4.08%	18	3.01%	0.288	0.592	0.115	0.383
no radiotherapy	547	38.71%	197.00	41.74%	143.00	41.69%	207.00	34.62%	0.026	0.989	0.017	0.031

The group of patients recommended for radiotherapy treatment based on the guidelines (T3 or T4 or N>0 and M0) was identified [9, 12] and numbered 767 patients (54.28% of the whole cohort). Within this group SCRT, RCT, postoperative radiotherapy or any form of preoperative radiotherapy (SCRT and RCT) were used more frequently than in the whole cohort in all periods (A, B, and C), with except for the use of RCT in period C. In this group there was a significant increase in the application of preoperative SCRT comparing period B to C (40.46% vs. 53.02%), while other forms did not differ significantly among the periods (Tab. 5).

The number of patients with histopathological stage pT0, pTis, or pT1 who received preoperative RCT were 3, 12, and 18 in periods A, B, and C respectively. They represented 10.71%, 28.57%, and 22.22% of patients with such staging in the subsequent time intervals. In the whole group of patients who received preoperative RCT, patients with staging pT0-1 represented 16.58%. Based on the guidelines patients with such staging should not receive radiotherapy, so this group probably represents patients who were qualified for the radiotherapy with higher staging and achieved near complete or complete response.

Table 5. Application of different types of radiotherapy in patients who should receive it (pT3/T4 or pN+ and M0).

	all		2013-2014		2015-2016		2017-2019		p chi2	A vs B	A vs C	B vs C
	n	%	n	%	N	%	n	%				
number of patients	767	100%	279	36.38%	173	22.56%	315	41.07%				
SCRT	371	48.37%	134	48.03%	70	40.46%	167	53.02%	0.029	0.116	0.225	0.008
RCT	111	14.47%	37	13.26%	31	17.92%	43	13.65%	0.339	0.178	0.890	0.209
any preoperative radiotherapy	482	62.84%	171	61.29%	101	58.38%	210	66.67%	0.155	0.539	0.173	0.690
postoperative radiotherapy	44	5.74%	20	7.17%	10	5.78%	14	4.44%	0.362	0.564	0.154	0.514
no radiotherapy	241	31.42%	88	31.54%	62	35.84%	91	28.89%	0.286	0.346	0.482	0.113

In patients with tumors localized >10cm from the anal sphincter and stage pT3/4N+M0, the only significant difference in the use of radiotherapy was present in the higher percent of patients treated with RCT in period C than A (19.51% vs. 4.35%; p = 0.027). The overall use of radiotherapy in this group was lower than in the whole cohort of patients pT3/4N+M0 – 23.91% vs. 61.29%, 27.27% vs. 58.38%, and 34.15% vs. 66.67% in periods A, B, and C respectively.

3.4 Oncological vs. non-oncological centers

Among included centers there were both oncological and non-oncological. A comparison of the groups of patients who should receive radiotherapy between oncological and non-oncological centers indicated that SCRT or any preoperative radiotherapy (SCRT or RCT) was more common in oncological centers in all periods. The percent of patients treated with preoperative RCT was significantly higher in oncological centers in periods A and B while in period C it was higher in non-oncological centers. Postoperative radiotherapy was more frequent in non-oncological centers, but the number of patients treated with this method was too small to be analyzed statistically.

In both oncological and non-oncological centers, there were no differences in tumor localizations when comparing time intervals. In all periods there was a higher percent of patients with tumors localized >10cm in non-oncological centers than in oncological, with statistically significant differences in periods A, C, and in the whole analyzed period. There was also a significant difference between the larger percent of patients with tumor localization 0-5cm in oncological centers than in non-oncological centers in period C and throughout the whole analyzed period.

In all periods the percent of R0 radicality of resection was higher in oncological centers than in non-oncological, with statistically significant differences in period C and in the whole time interval (Tab. 6.)

Table 6. Comparison between oncological and non-oncological centers in the application of different types of radiotherapy, R classification, and tumor localization.

Comparing periods, A and B to C in oncological centers, there was a significant increase in the use of SCRT (A – 64.81%, B – 56.90%, C – 81.29%; p<0.001) and a decrease in the use of RCT (A – 20.37%, B – 27.59%, C – 7.19%; p<0.001). In non-oncological centers, there was a significant increase in the application of RCT with time (A – 8.77%, B – 13.39%, C – 18.75%; p=0.025).

Discussion

This study aimed to evaluate the treatment of rectal cancer in Poland in the realm of the OP implementation, by analyzing changes in the treatment and its coherence with the guidelines.

The results of this trial indicate that in subsequent time intervals, the percent of patients with lower pT stages was noticeably increasing and the percent of patients with a higher stage was decreasing, while the demographic data of patients or the types of performed procedures did not differ significantly among time periods. There was a discernible improvement in the quality of surgical treatment with time. The percent of procedures with stoma, in the groups of patients M0 with tumor localization 0-5cm from the anal sphincter was significantly decreasing as well as the number of resected lymph nodes was increasing. The percent of R0 radicality of resection also was the highest in period C, with a statistically significant difference between periods B and C. In the whole cohort, the overall use of preoperative radiotherapy was increasing, and in the isolated group of patients pT3/4 or pN+ and M0, the significant difference referred only to the SCRT.

Our research indicated that coordinated standards of care have had a positive impact on rectal cancer treatment. Several studies evaluating the standards of rectal cancer care were performed in other countries [5, 13–24]. Many of which have underlined the diversity of the national and international outcomes [4, 5, 11, 21, 25] and the crucial role of high-quality auditing [20, 22]. The implementation of clearly defined standards of rectal cancer care, not only enhances the adherence to the guidelines but facilitates reporting of further outcomes.

One major part of the OP in Poland are obligatory MDT meetings. Based on the outcomes of this study we hypothesize that they might have had a significant impact on the increase of the use of radiotherapy. Multiple research have investigated MDT's impact on rectal cancer treatment [13–16, 26–32]. Most of the studies prove that MDT meetings have a positive impact on the treatment of rectal cancer, including the therapeutic process and oncological outcomes [13, 29, 30]. Some studies also report an increase in the use of radiotherapy in patients with rectal cancer, what is coherent with our study results [16, 31]. Nevertheless, some of the studies report that the MDT meetings did not improve the quality of the treatment of rectal cancer [15, 28] or they have even extended the length of time to treatment implementation [27].

The overall use of radiotherapy in our trial was increasing, which we interpreted as a positive change, and reached 62.37% in period C, which was comparable with the literature results – Dutch Surgical Colorectal Audit reports 64.4% in 2014 [24], while Dutch ColoRectal Audit 54.3% in years 2014-2017 [23]. However, the consistency of these reports and our trial is limited. Despite corresponding results of the use of SCRT, the use of RCT was lower in our trial, reaching 16.91% in period C while in cited studies, it was 30.5% (2014-2017) [23] and 37.6% (2009-2014) [24]. Furthermore, in both Dutch studies a significant decrease in the use of radiotherapy over time was reported. In the years 2011-2013, before the decrease, it had reached as high as 82.3% of overall use [23]. The decrease appeared after the revision of the guidelines, which abolished the application in low-risk rectal cancer, defined as cT1-3N0, with extramural invasion ≤5 mm and a distance to the mesorectal fascia >1 mm, based on the preoperative MRI [23, 24]. As we did not obtain data on the cTNM and the extramural infiltration or distance from mesorectal fascia, the analysis of this specific group was not possible. The discrepancies between studies may result from the use of different guidelines for the treatment of rectal cancer or the differences in the tumor advancement in different national populations.

The increasing number of patients with lower pT stages, could have been caused by the development of the colonoscopy screening, to which patients have a broad access in large cities, where centers included in this study are located. As the utilization of preoperative radiotherapy was increasing, the lower tumor advancement in pathological specimen could potentially be associated with the response to radiotherapy.

The reduced number of the procedures with stoma may stem from the growing surgeons' experience in the field of rectal surgery, but it could also be a consequence of the increased use of radiotherapy, leading to downsizing of the tumor and enhancing the surgical possibilities.

In conclusion, this study shows that over time since the implementation of the OP in Poland the pT stage in patients operated due to rectal cancer was lower and there was a significant increase in the use of radiotherapy and an improvement in surgical treatment. Nevertheless, the standards of oncological care are very complex concepts that are very difficult to compare due to huge differences both within and between the national healthcare systems. Due to this reason, making a definitive comparison between our results and the results of audits from other countries is extremely challenging, and additional data would be necessary to enable such a comparison.

Limitation of the study:

The study has some limitations. The retrospective character of the study impeded the cofounders' control. The information about postoperative outcomes and long-term follow-up which are crucial for cancer treatment evaluation, were unavailable. There was only one oncological center included which may skew the results of the comparison between oncological and non-oncological centers. There was also no QoL and cost-effectiveness assessment both of which play an important role in planning the cancer healthcare plan.

Conclusions

In the whole cohort, there is a significant increase in the use of preoperative radiotherapy and a decrease in the pT stage since the implementation of OP. Some factors indicating the improvement of the surgical treatment were also found. Nevertheless, these relations are indirect and more data pertaining patients' outcomes should be gathered for further conclusions.

Declarations

Ethical Approval:

The study was approved by the Bioethics Committee of Jagiellonian University in Krakow, Poland (number of approval: 1072.6120.120.2021).

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Availability of data and materials:

Not applicable.

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Table

Table 6 is available in the Supplementary Files section

Figures

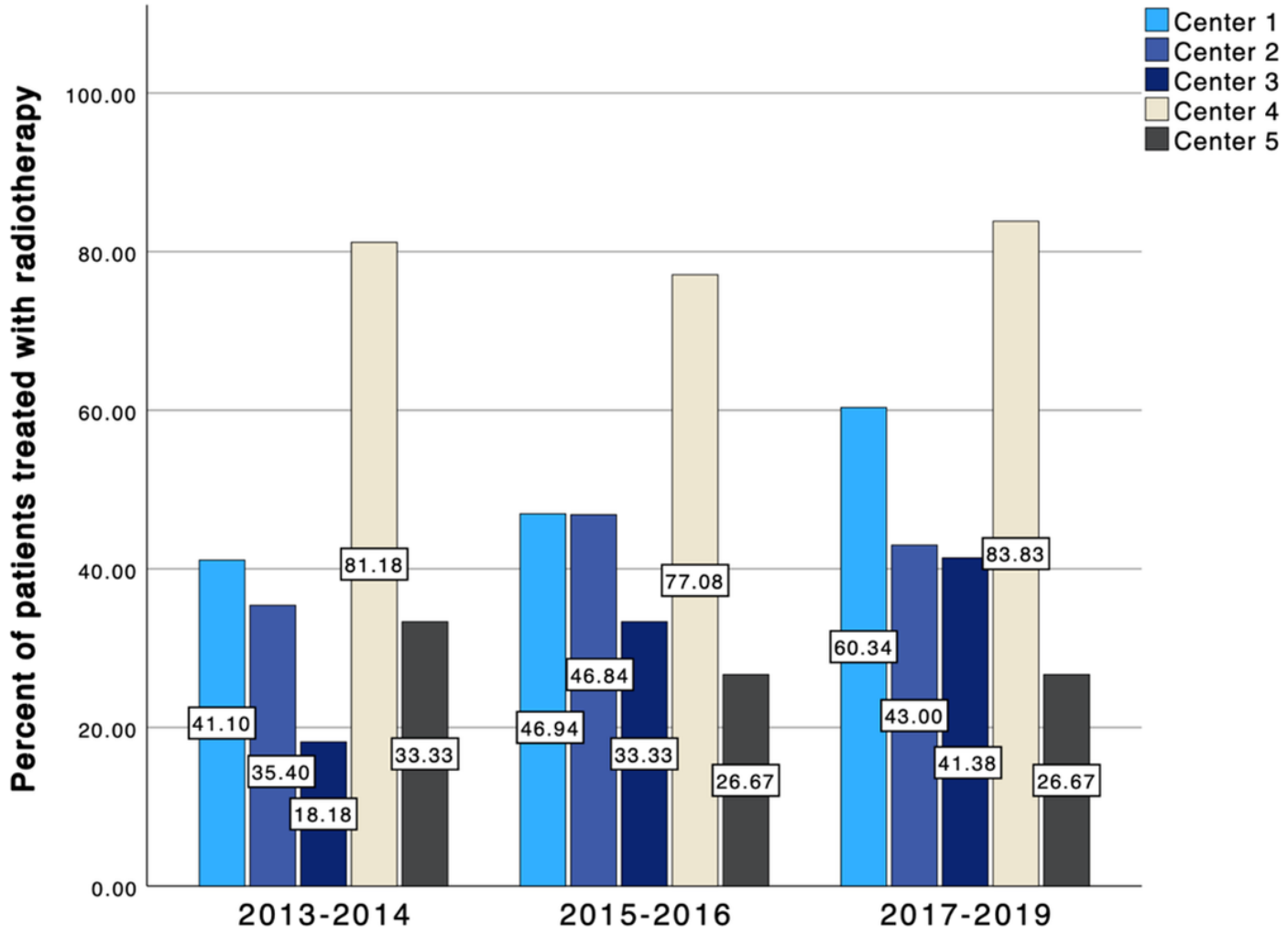

Figure 1

Application of preoperative radiotherapy in different centers in time intervals.

Supplementary Files

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