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The pan - COVID - AGICT study. The impact of COVID-19 pandemic on surgically treated pancreatic cancer patients. A multicentric Italian study

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ABSTRACT

Background: In this article we aimed to perform a subgroup analysis using data from the COVID-AGICT study, to investigate the perioperative outcomes of patients undergoing surgery for pancreatic cancers (PC) during the COVID-19 pandemic.

Methods: The primary endpoint of the study was to find out any difference in the tumoral stage of surgically treated PC patients between 2019 and 2020. Surgical and oncological outcomes of the entire cohort of patients

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were also appraised dividing the entire peri-pandemic period into six three-month timeframes to balance out the comparison between 2019 and 2020.
Results: Overall, a total of 1815 patients were surgically treated during 2019 and 2020 in 14 Italian surgical Units. In 2020, the rate of patients treated with an advanced pathological stage was not different compared to 2019 ($p = 0.846$). During the pandemic, neoadjuvant chemotherapy (NCT) has dropped significantly (6.2% vs 21.4%, $p < 0.001$) and, for patients who didn't undergo NCT, the latency between diagnosis and surgery was shortened (49.58 ± 37 days vs 77.40 ± 83 days, $p < 0.001$). During 2020 there was a significant increase in minimally invasive procedures ($p < 0.001$). The rate of postoperative complication was the same in the two years but during 2020 there was an increase of the medical ones (19% vs 16.1%, $p = 0.001$).
Conclusions: The post-pandemic dramatic modifications in healthcare provision, in Italy, did not significantly impair the clinical history of PC patients receiving surgical resection. The present study is one of the largest reports available on the argument and may provide the basis for long-term analyses.

1. Introduction

On March the 9th, 2020, in Italy was established the first lockdown to deal with what would be declared by the World Health Organization (WHO) a few days later, on March the 11th, as the global Coronavirus Disease 2019 (COVID-19) pandemic [1–3].

Italy was one of the most affected countries, especially during the first wave of virus spread in Europe, with serious economic and social consequences.

The need to direct resources and capacity toward treating COVID-19 patients resulted in significant reduction or suspension of other elective and emergency healthcare provision, including cancer care. This dramatically impacted on routine diagnostic examinations, screening programs, elective oncological treatments and emergency surgery [4–8]. Actually, how best to manage cancer patients became a major concern [9,10].

Pancreatic cancer (PC) is still one of the deadliest malignancies in Western Countries. However, unlike other gastrointestinal cancers, PC is less frequently identified by means of screening programs, with most patients being diagnosed with specific symptoms at presentation [11].

Timely surgical resection is the mainstay of treatment for localized PC and prognosis is largely dependent on early presentation and prompt diagnosis [12,13]. Such clinical characteristics, together with the need for a specific multidisciplinary approach, in dedicated, high-volume facilities has posed particular difficulties during the pandemic era [11].

A large, cross-sectional study has examined changes in the number of patients with newly diagnosed malignancy before and during the pandemic in the United States. As for PC, the weekly number of newly identified patients demonstrated a 25 percent decline, which was significantly lower as compared to that shown by other malignancies such as breast, colorectal, and gastric cancer [14]. A recent, French multicenter cohort study similarly reported a referral fall by 29 percent of newly diagnosed PC patients due to the COVID pandemic [15]. However, clinical implications of such delays in PC diagnosis remain essentially uncertain and available evidence on the argument is still limited and discordant [9,11,15,16]. Some authors have reported that the percentage of localized disease has decreased over time, with a progressive rise in the number of patients presenting at advanced stages following the pandemic outbreak [11]. On the contrary, other analyses did not reveal any tumor stage shift or impairment in the treatment intent of PC patients [15,16].

In particular, specific data on the clinical outcomes of surgically resected PC patients before and after the pandemic are limited [9,17]. Accordingly, in this article we aimed to perform a subgroup analysis using data from the COVID-Advanced Gastrointestinal Cancer Surgical Treatment (AGICT) study [4] to investigate whether the COVID-19 pandemic impaired the clinical history of PC patients.

2. Methods

Data were collected from the COVID-AGICT database, an Italian, national multicentric retrospective cohort study including adult patients undergoing surgery for colorectal, gastroesophageal or pancreatic cancers from January 2019 to December 2020 across 62 Italian surgical divisions. The AGICT study included all adult patients surgically treated for localized, locally advanced, or metastatic cancers with curative or palliative intent during the study period. Exclusion criteria were patients with multiple tumors and recruiting centers that were not able to provide comprehensive data for both 2019 and 2020 [4]. The research was approved by the ethics committee of the coordinating center (reference number 18886) and registered at ClinicalTrial.gov (NCT04686747).

Data concerning PC patients were extracted to be investigated. For each patient the following data were collected: age, BMI, ASA score, Charlson Comorbidity Index (CCI) score, method of diagnosis, neoadjuvant treatments, time interval from diagnosis to surgery, disease resectability, surgical approach, length of hospital stay (LOS), postoperative morbidity (according to the Clavien-Dindo classification), 30-day readmission, and 30-day mortality. Oncological outcomes were also appraised, including tumor stage, margin resection status, adjuvant therapy and time interval from surgery to adjuvant treatments.

Patients were divided into early and advanced stages according to clinical and pathological data. Were considered as having early stages all patients with non-nodal, non-metastatic disease who received radical (i.e. R0) resection. The 8th edition of the American Joint Committee on Cancer (AJCC) Staging System was employed to classify pTNM stages of patients with pancreatic ductal adenocarcinoma (PDAC).

The entire peri-pandemic period was divided into six three-month timeframes to balance out the comparison between 2019 and 2020. In particular, the pre-lockdown year 2019 was divided into.

- T1 (from march 8 to june 8, 2019)
- T2 (from june 9 to september 8, 2019)
- T3 (from september 9 to december 8, 2019)

Whilst the pandemic lockdown year 2020 was divided into.

- T4 (from march 8 to june 8, 2020)
- T5 (from june 9 to september 8, 2020)
- T6 (from september 9 to december 8, 2020)

The primary endpoint of the study was to find out any difference in the tumoral stage of surgically treated PC patients between 2019 and 2020.

Surgical and oncological outcomes of the entire cohort of patients were also appraised and compared between pre- and post-pandemic breakdown.

2.1. Statistical analysis

Quantitative variables are presented as mean ± standard deviation while categorical variables are reported as percentages and absolute values. Univariate analysis included Student's *t* tests, Mann–Whitney *U* test and χ^2 test. All tests were two-tailed and a p value ≤ 0.05 was considered statistically significant. All data were analyzed using IBM

SPSS Statistics, version 25 (SPSS Inc., Chicago, IL, United States).

3. Results

3.1. Demographic data

Overall, the COVID-AGICT study enrolled 8250 patients: a total of 1815 PC patients from 14 recruiting centers were identified and eventually included in the analysis for data extraction (Fig. 1).

The analysis of demographic data showed no differences between the two years in terms of mean age (65 ± 12.2 years), mean BMI (24.8 ± 3.9), preoperative ASA score (49% ASA 1–2, 35.2% ASA 3–4) and Charlson Comorbidity Index score (4.8 ± 1.8).

The rate of urgent diagnosis was 43.9%; 92.5% of patients resulted to be resectable, 92.4% with curative intent and 24.5% with minimally invasive approach (MIS). 25.2% of the population underwent neoadjuvant therapy.

Pathologically, 62.6% patients had diagnosis of PDAC, 10.1% pancreatic neuroendocrine tumor (pNET), 6% intrapapillary mucinous neoplasm (IPMN), 3.5% cholangiocarcinoma (CC) and 17.8% patients had other conditions (e.g. pancreatic localization of metastatic renal cell carcinoma).

Despite slight differences amongst individual time frames, no differences were found at specific analysis comparing corresponding periods (T1-T4, T2-T5, and T3-T6) between 2019 and 2020 on ASA score (Fig. 2) and CCI score (Fig. 3).

The number of pancreatectomies fell from 682 surgeries in 2019 (from T1 to T3) to 399 in 2020 (from T4 to T6), with an overall reduction in surgical activity of 41.5%. In particular, direct analysis indicated that surgical volumes progressively decreased between the corresponding trimesters of 2019 and 2020 by −33% (T1-T4), −32% (T2-T5), and -60% (T3-T6) (Fig. 4).

As for pancreatic diseases, there was a significantly different redistribution of indications for surgery before and after the pandemic. In particular, surgeries for PDAC, CC and IPMN increased (by +1.72%, +29%, and+19%, respectively), while pNET resections declined by 28%.

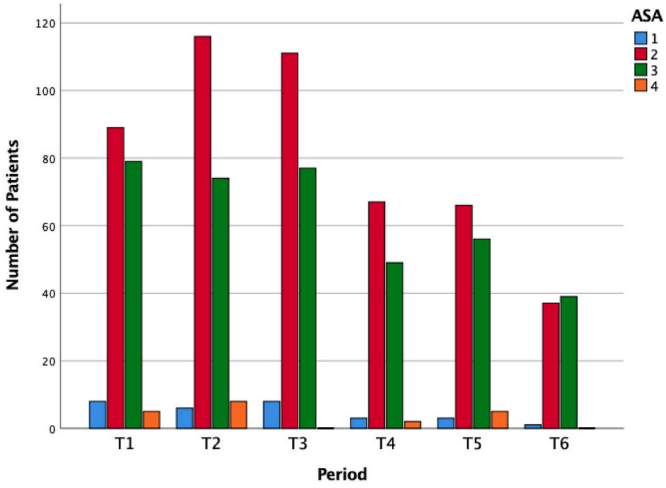

Fig. 2. ASA score distribution per phase.

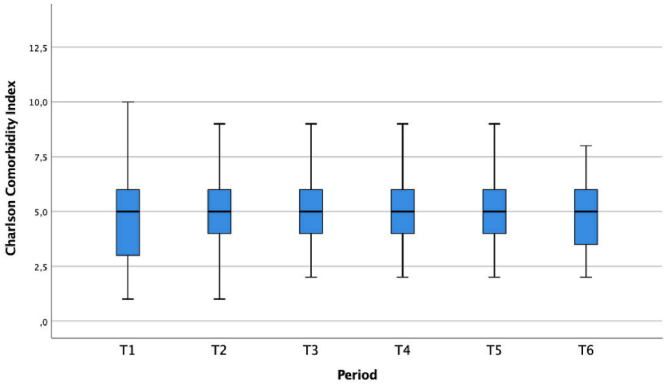

Fig. 3. CCI score distribution per phase.

Fig. 1. Geographical distribution of COVID-AGICT study's pancreatic centers. Blue: coordinating center.

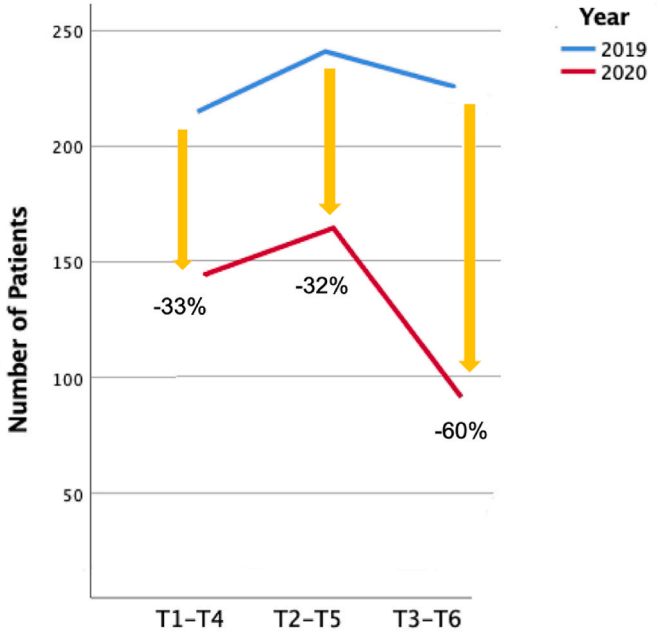

Fig. 4. Volume variation of pancreatic surgeries per phase during 2020 as compared to 2019.

Concerning modalities of diagnosis, the rate of urgent diagnosis was 50% during the pandemic, compared to 46.6% in 2019, this difference did not elicit statistical significance (p = 0.676). There was a statistically significant lower percentage of neoadjuvated patients in 2020 (6.2%) as compared to 2019 (21.4%) (p < 0.001). Indeed, among patients receiving upfront surgery, the delay between diagnosis and pancreatectomy was lower after the pandemic outbreak than in 2019, being 49.58 ± 37 days and 77.40 ± 83 days respectively (p < 0.001).

3.2. Primary endpoint

During 2019 93% of the patients resulted to be resectable while during 2020 the patients resectable resulted to be 93.5% (p = 0.943). This lack of difference was quite the same regarding the intention of treatment, recording 93.1% of curative procedures in 2019 compared to 93.2% in 2020 (p = 0.957).

For patients treated with a curative intent, it was then analyzed the rate of R0 resection that resulted to be the same in the two years, being 75.5% during the pandemic period and 75.4% in 2019 (p = 0.623).

As regards the number of lymph nodes harvested, the mean was 33 ± 19.2 in 2019 and 31 ± 18 in 2020 (p = 0.059), the rate of positive nodes on the total nodes resected were respectively 55.9% and 56.7% (p = 0.998).

According to these results the rate of patients operated at an advanced stage (lymph nodes positivity and resection margin > R0) during the pandemic year was 60.7%, while during 2019 it was 60.1%, this difference was not statistically significant (p = 0.846).

About patients treated for pancreatic ductal adenocarcinoma there was no difference in stages between the pre-pandemic and pandemic period (p = 0.224). In particular, tumor stages appeared to be more advanced in T5, nevertheless, comparing T5 with its corresponding pre-pandemic period, T2, it was confirmed that the difference between them did not reach significance values (p = 0.104). Similarly there was no difference between T1 and T4 (p = 0.803) and between T3 and T6 (p = 0.921) (Fig. 5).

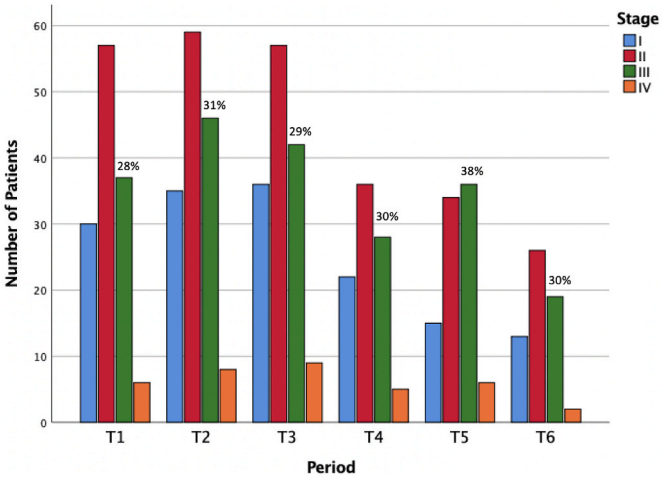

Fig. 5. PDAC pathological stages per phase (percentage for stage III).

3.3. Secondary endpoints

3.3.1. Perioperative outcomes

In relation to the surgical approach (defining laparoscopic, robotic and roboscopic approaches as MIS, ''minimally invasive surgery''), a statistically significant difference was recorded between the two years (p < 0.001), with an increase in minimally invasive procedures during the pandemic period.

Mean LOS was not statistically different between 2019 and 2020 (18.4 ± 17 vs 18 ± 16 days, p = 0.706).

The analysis of postoperative complications did not demonstrate any significant difference between 2019 and 2020, including both overall morbidity (64.8% vs. 63.8%, p = 0.2) and major morbidity (22.7% vs. 18.5%, p = 0.112).

There was a statistically significant variation in the type of postoperative morbidity between 2019 and 2020. In particular, the rate of surgical complications decreased from 26% to 17.7% (p = 0.001), while the incidence of medical complications increased from 16.1% to 19% (p = 0.001) (Fig. 6).

Thirty-day readmission rate occurred the same in both years (6.7% in 2019 vs 7.3% in 2020, p = 0.777); similarly for the thirty-day mortality rate (3.4% in 2019 vs 3% in 2020, p = 0.731).

3.3.2. Early oncological outcomes

The rate of adjuvant treatments was not statistically different between the two years, being 30.4% in 2019 and 31.7% in 2020 (p = 0.966) and the mean time from surgery to the start of adjuvant therapy

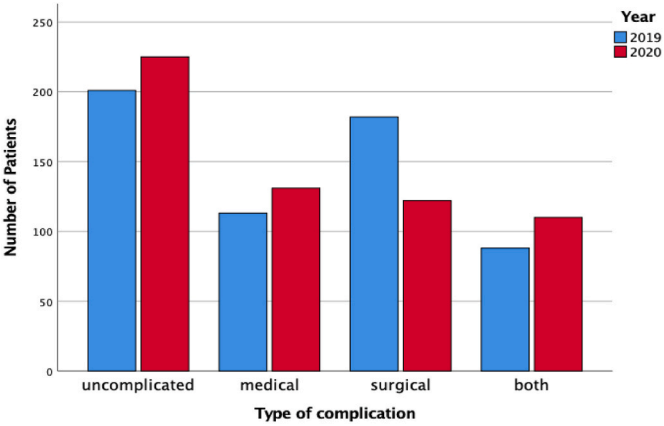

Fig. 6. Type of 30-day complication.

was quite longer during the pandemic period, being 73.05 ± 29.6 days against 65.84 ± 29.4 days in 2019 (p = 0.060).

4. Discussion

The results of our multicentric cohort study reveal that pandemic-related modifications and redistributions of healthcare provision in Italy did not significantly affect the rate of PC patients operated at an advanced stage. Notably, neither the rate of resectable disease, nor the rate of pancreatectomies undertaken with curative intent was statistically different along the year before and after the pandemic outbreak. Interestingly, amongst patients receiving curative resection, no difference was found in terms of lymph node harvest and rate of negative surgical margins. Similar findings were demonstrated when specifically focusing on PDAC patients, for which no differences in clinical presentation were reported, despite a relative increase in the prevalence of stage III diseases (Fig. 5).

One of the most interesting, yet evident data in our analysis is the dramatic decrease in surgical resections of PC patients following the pandemic outbreak. Such a reduction in newly referred cases of PC in 2020 is consistent with that demonstrated by several reports across the World and Europe in particular [9,15,18]. However, evidence on the clinical outcomes of surgically treated PC patients is still scarce and controversial [4,15,19,20].

Some of the data we observed are easily explained by the recommended criteria for the treatment of oncological diseases during the pandemic [9,15,20]. Actually, the drop of pNET pancreatectomies is in line with other recent reports and with the prioritization of frankly malignant conditions such as PDAC or CC [9,18,21] due to their higher mortality rate.

Some other findings, such as the relative data concerning the delivery of anticancer therapies are still unclear [9,18,21]. Approximately one third of centers involved in a recent, large survey in the United Kingdom vary their treatment approach for PC patients from an upfront surgical pathway to neoadjuvant therapies, in line with the growing evidence supporting preoperative anticancer treatment [20]. On the contrary, our analysis indicates that the rate of neoadjuvant treatments decreased in 2020 as compared to pre-pandemic practice, and the delay between diagnosis and surgery also reduced. The rationale supporting this data is difficult to argue and is likely to be multifactorial. In fact, the increased proportion of patients receiving surgery for malignancy in respect of low-aggressive neoplasm in 2020 may justify a higher rate of neoadjuvated patients, rather than the observed data. Nevertheless, concerns from oncologists regarding SARS-CoV2 infection among patients receiving chemotherapy together with the logistical priorities recommended to reduce inpatient treatment regimens may be at the basis of such observation. The French CAPANCOVID cohort study investigating the impact of the pandemic on disease stage and treatment for PDAC patients disclosed that as compared to patients with pre-COVID diagnosis of PC, post-COVID diagnosis were associated with a decreased rate of administration of neoadjuvant or induction chemotherapy regimen (24.7% vs. 17.6%), with concomitant increase in the application of upfront surgery (13% vs 15.5%) [19]. On the contrary, a large, multicentric analysis conducted in Italy involving a total of 1423 patients documented a significant reduction in the rate of administration of adjuvant therapies in the first pandemic trimester compared to 2019 standards [9]. It is obvious that the actual clinical implications associated with such modifications in the treatment pathways of surgical PC patients remain essentially unknown and discrepant across studies. Only prospective data collection on long-term outcomes will define the real consequences of this re-shaped scenario.

With reference to the surgical approach employed, as confirmed by the MIS-COVID-AGICT study [22], our data showed a significant increase in the application of MIS as compared to the pre-pandemic practice. During the initial spread of COVID-19 pandemic any aerosol-generating procedure has been considered a possible source of viral spread and the safety of MIS has been a matter of debate [18–21]. Different surgical societies supplied recommendations with regards to the use of MIS during the COVID-19 pandemic, often returning non-univocal recommendations [23–27]. However, despite some initial skepticism in the very first diffusion of the pandemic, the rate of application of MIS continued to rise during the subsequent phases, owing to the fact that the well-known advantages of MIS on the clinical course of better selected patients substantially exceeds the risk of potential viral transmission [25,27].

Regarding the difference of postoperative complication, the decrease of the surgical ones could be due to a higher selection of patient fit for surgery. Unfortunately, not all centers clearly explained the types of medical complications experienced and so it was not possible to assess whether their increase was linked to COVID or not.

4.1. Limitations

This study acknowledges a number of limitations. First, it was retrospective in nature. Second, only surgical patients were included: given the critical reduction in surgical caseload along the course of the pandemic, it is likely that a considerable percentage of patients was excluded due to missed or delayed diagnosis. Third, some data were not available or detailed enough to allow specific analysis, including data on tumor biology and surgical techniques employed by different recruiting centers; this may have influenced our final outcomes. Finally, it should be acknowledged that long term-outcomes, especially oncological follow-up, are lacking.

4.2. Conclusions

Our large, multicentric analysis suggests that post-pandemic dramatic modifications in healthcare provision in Italy did not significantly impair the clinical history of PC patients receiving surgical resection. The present study is one of the largest reports available on the argument, and may provide the basis for long-term analyses.

Conflict of interest disclosures

The authors have no conflicts of interest or financial ties to disclose related to the research presented.

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CRediT authorship contribution statement

Maria Pia Federica Dorma: Writing – original draft, Software, Project administration, Investigation, Formal analysis, Data curation. **Giuseppe Giuliani:** Writing – review & editing, Supervision, Resources, Methodology, Data curation, Conceptualization. **Francesco Guerra:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Data curation, Conceptualization. **Francesco Santelli:** Formal analysis, Data curation. **Giulia Turri:** Resources, Investigation. **Corrado Pedrazzani:** Resources, Investigation. **Emanuele Federico Kauffmann:** Resources, Investigation. **Ugo Boggi:** Resources, Investigation. **Leonardo Solaini:** Resources, Investigation. **Laura Mastrangelo:** Resources, Investigation. **Gregorio Di Franco:** Resources, Investigation. **Luca Morelli:** Resources, Investigation. **Serena Langella:** Resources, Investigation. **Alberto Brolese:** Resources, Investigation. **Andrea Belli:** Resources, Investigation. **Enrico Pinotti:** Resources, Investigation. **Alessandro Coppola:** Resources, Investigation. **Fabrizio Di Benedetto:** Visualization, Validation, Supervision. **Alessandro Esposito:** Software, Formal analysis. **Matteo De Pastena:** Resources, Investigation. **Chiara Cova:** Resources, Investigation. **Laura**

Mastrangelo: Resources, Investigation. **Gregorio Di Franco:** Resources, Investigation. **Giovanni Ferrari:** Resources, Investigation. **Serena Langella:** Resources, Investigation. **Roberta La Mendola:** Resources, Investigation. **Mohamnad Abu Hilal:** Resources, Investigation. **Norma Depalma:** Resources, Investigation. **Stefano D'Ugo:** Resources, Investigation. **Marcello Giuseppe Spampinato:** Resources, Investigation. **Marco Frisini:** Resources, Investigation. **Alberto Brolese:** Resources, Investigation. **Andrea Belli:** Resources, Investigation. **Antonello Deserra:** Resources, Investigation. **Alessandro Cannavera:** Resources, Investigation. **Andrea Sagnotta:** Resources, Investigation. **Stefano Mancini:** Resources, Investigation. **Enrico Pinotti:** Resources, Investigation. **Irene Pecora:** Resources, Investigation. **Andrea Coratti:** Visualization, Validation, Supervision. **All collaborative group:** Acquisition, analysis or interpretation of data

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