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Application of magnetic resonance imaging with intraoperative color Doppler ultrasound in the treatment of patients with polyacrylamide hydrogel injected for breast augmentation: a retrospective study of 204 cases for 12 years

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Purpose: Polyacrylamide hydrogel (PAHG), which had been used widely for breast augmentation, has been banned for more than 15 years. Patients who had been injected PAHG for breast augmentation need evacuation surgery to remove as much as possible. To provide a series of diagnosis and treatment process MRI and intraoperative color Doppler ultrasound are combined for maximal removal of PAHG.
Methods: The patients who received evacuation surgery in Peking University Third Hospital from 2010 to 2022 after PAHG injection for breast augmentation were included in this research. MR scanning was performed preoperatively and postoperatively in some of these patients and color Doppler ultrasound was applied to help evacuate PAHG intraoperatively. The mean clearance rate of PAHG was calculated according to the MRI outcomes.
Results: Two hundred and 4 patients had received evacuation surgery after PAHG injection for breast augmentation with an average age of 42.8 years and an average body mass index of 21.2 kg/m^2. The average PAHG retention time was 13.5 years. Among them, 52 patients underwent pre- and postoperative MRI scanning. The mean three-dimensional (3D) volume of PAHG was 684.8 mL (range, 350.0–1,123.9 mL), and the average residual 3D volume of PAHG was 53.7 mL (range, 12.4–98.3 mL). The mean clearance rate was 92.1%.
Conclusion: MRI and intraoperative color Doppler ultrasound can provide effective and precise location information of PAHG for evacuation surgery, which is a reliable method to ensure the maximal removal of PAHG.
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Key Words: Breast Implantation, Magnetic resonance imaging, Polyacrylamide hydrogel, Ultrasonography

INTRODUCTION

Polyacrylamide hydrogel (PAHG; trade name: Interfall, Amazingel, etc.) as a permanent soft tissue filler had once been utilized clinically in China since 1997. However, due to its potential toxicity to the human body [1] and complications

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associated with PAHG injections reported extensively in the literature [2-5], the government of China has banned using it since 2006 and advocated removing the injection material as early as possible even for asymptomatic patients [6]. There has been a consensus that mere PAHG evacuation surgery could cure these patients [6]. However, the mobility of hydrogel [7] and incorrect injection methods lead to uneven distribution of PAHG, which makes it difficult to remove completely during the surgery. Therefore, the method of removing the greatest amount of PAHG in order to achieve a better prognosis remains an urgent task to be solved.

The experience of PAHG removal has been extensively reported. In the early years, most of the reports were based on MRI, and the surgery was performed according to the distribution of PAHG shown by the images. However, there is no quantitative evaluation index to determine the effectiveness of surgery [8]. In the last decade, most of the literature used Breast-Q [9], a patient-reported outcome scale as a quantitative evaluation index to evaluate the surgical results in terms of the improvement of satisfaction with breast appearance, psychological well-being, sexual well-being, and physical well-being. There is no reference value to assess the efficiency of PAHG removal by Breast-Q. Encouragingly, a report on the application of Mimics reconstruction to assist in measuring the distribution of PAHG in patients was published in 2014 [10], which provided a remarkably effective method of measuring PAHG volume. However, the efficiency of PAHG removal was not evaluated in this way.

Besides this, the reliability of MRI and intraoperative color Doppler ultrasound in surgery of PAHG removal has been confirmed. The articles mentioned above confirmed the value of MRI in PAHG extraction procedures [6,8,9,11]. Though we believe that the value of MRI deserves to be recognized, it still has its own limitations that it cannot provide real-time images for intraoperative reference. The sole application of MRI to facilitate the removal of PAHG does not work effectively, resulting in excessive residual injections and even secondary work or multiple surgeries.

In this study, we combine MRI with intraoperative color Doppler ultrasound to facilitate PAHG evacuation surgery and assess the removal efficiency of PAHG through objective indicators. The purpose of this study is to investigate the efficiency of this new method in the treatment of patients who had received PAHG injections for breast augmentation.

METHODS

Ethics statement

This study was approved by the Medical Science Research Ethics Committee of Peking University Third Hospital (No. IRB00006761-M2020062). Informed consent was obtained from all patients. All methods performed in this study were in accordance with the Declaration of Helsinki.

Patients

Between 2010 and 2022, the patients who underwent evacuation surgery after PAHG injection for breast augmentation in the Department of Plastic Surgery of Peking University Third Hospital were included in this research. Patients with systemic features (e.g., fever or leukocytosis) or local signs of infection were not included in this study. The trade names of the materials injected were either Interfal (made in Ukraine; Ukraine Interfall Co., Ltd) or Amazingel (made in China; NanFeng Medical Science and Technology Development Co., Ltd.). The volume and location of the injected materials could not be provided by most of the patients because of surgical records missing or being not well documented.

Each patient underwent magnetic resonance (MR) scanning (uMR770 3.0 T, United-Imaging) preoperatively, to determine the location of the PAHG. The criteria scheme included axial T2-weighted images with and without fat depression and sagittal T1- and T2-weighted images with fat depression. In the axial T2-weighted images with fat depression (Fig. 1), PAHG shows a bright high signal because of its hydrophilic property, which is significantly contrasted with surrounding tissues, and clearly shows its location. Because of the hydrophilic property, PAHG presents image characteristics of low echo under real-time ultrasound exploration (Fig. 2). Therefore, PAHG is shown as liquid dark areas or encapsulated cysts in the ultrasound images.

Surgical technique

An open evacuation operation via semi-periareolar or inframammary fold incisions was performed under general

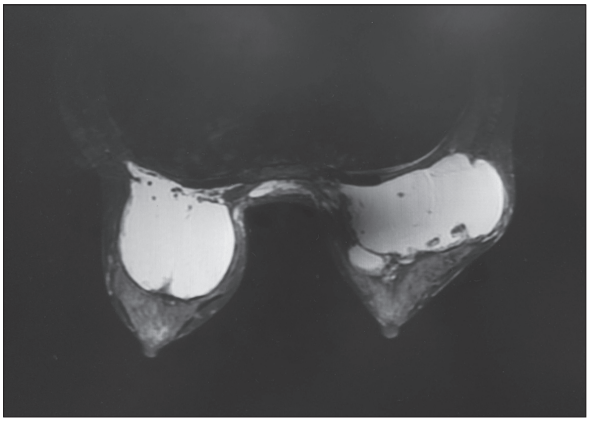

Fig. 1. The MRI of breasts with polyacrylamide hydrogel (PAHG) injection. In the axial T2-weighted images with fat depression, PAHG shows a bright high signal because of its hydrophilic property, which is significantly contrasted with surrounding tissues, and can clearly show its location.

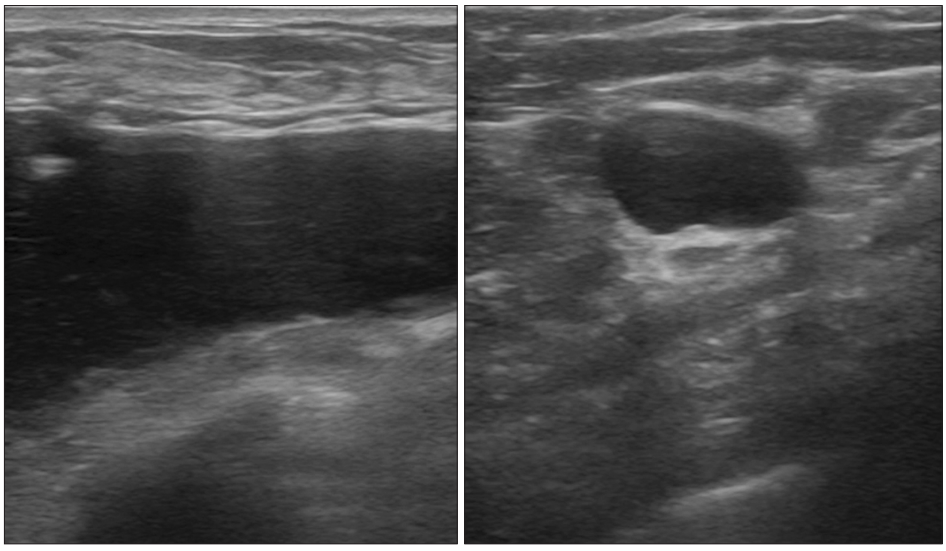

Fig. 2. The intraoperative color Doppler ultrasound image of breasts with scattered distribution of polyacrylamide hydrogel (PAHG). Because of the hydrophilic property, PAHG presents the image characteristics of low echo under real-time ultrasound exploration. Therefore, PAHG is shown as liquid dark areas or encapsulated cysts in the ultrasound images.

anesthesia. The dissection was carried out under the subcutaneous tissue to expose the mammary gland. According to the images shown by MR, an incision was made through the mammary gland at the lower pole of the breast until the main cystic capsule of PAHG was exposed. The foreign substances containing PAHG were drawn out by breaking the capsule of the major cystic cavity. The scattered cystic cavities of PAHG detected by the MRI were not as easy to locate as the main cystic cavity intraoperatively. Under these circumstances, intraoperative color Doppler ultrasound as guidance was utilized to locate the subcutaneous cysts. If the cysts were close to the skin, the injection of a saline solution and aspiration through a fine needle under the guidance of the ultrasound was effective. If the cysts were close to the main cystic cavity, PAHG could be removed by endoscopic dissection in the main cystic cavity along a fine needle that penetrated from the skin into the main cavity under the guidance of the ultrasound (Supplementary Video 1). The surrounding tissues as well as space emptied of the injected materials were repeatedly irrigated with saline solution to maximize the efficacy of the surgical PAHG removal. All the patients were sampled during the operation and the samples were sent for pathogenic examination.

After hemostasis, placement of vacuum surgical drains and closure of the wounds were conducted. The drains were maintained until the drainage was less than 20 mL per day.

Three-dimensional volume calculation through the reconstruction of magnetic resonance

The MR scanning was applied for a portion of patients postoperation. The pre- and postoperative DICOM (Digital Imaging and Communications in Medicine) images of the MR scans were imported into Mimics software (Materialise Co.). The axial T2-weighted images with fat suppression were selected for reconstruction. Then, a proper threshold was chosen to label PAHG on the basis of the images without fat suppression, and a three-dimensional (3D) reconstruction was processed by Mimics software, then the volume of PAHG could be calculated (Fig. 3). The 3D volume of PAHG pre- and postoperative could be known, and the clearance rate of PAHG could be calculated to evaluate the efficiency of the surgery procedure.

Statistical analysis

The measurement data were expressed as mean ± standard deviation. All the data were analyzed using IBM SPSS Statistics ver. 25.0 (IBM Corp.).

RESULTS

Two hundred and 4 patients were involved in this study. The average age was 42.8 years (23.0–62.0 years), and the average body mass index was 21.2 kg/m^2 (16.5–25.4 kg/m^2). The average time elapsed from the initial PAHG injection to the PAHG removal in our hospital was 13.5 years (2.0–21.0 years). PAHG was detected in the subglandular plane solo of 60 patients; subglandular and subcutaneous planes of 35 patients; subglandular, intra- and submuscular planes of 67 patients; subglandular, subcutaneous, intra- and submuscular planes of 35 patients; intra- and submuscular only of 7 patients. Most of the patients were asymptomatic who sought PAHG removal surgery due to anxiety about the potential damage (39.7%). Other indications for removal were as follows: (1) 69 patients (33.8%) with distending pain discomfort; (2) 45 patients (22.1%) with complaints of indurations; (3) 19 cases (9.3%) with injection displacement; and (4) 5 cases (2.5%) with complaints of residue of PAHG. Fourteen patients (6.9%) presented 2 or more symptoms (Table 1).

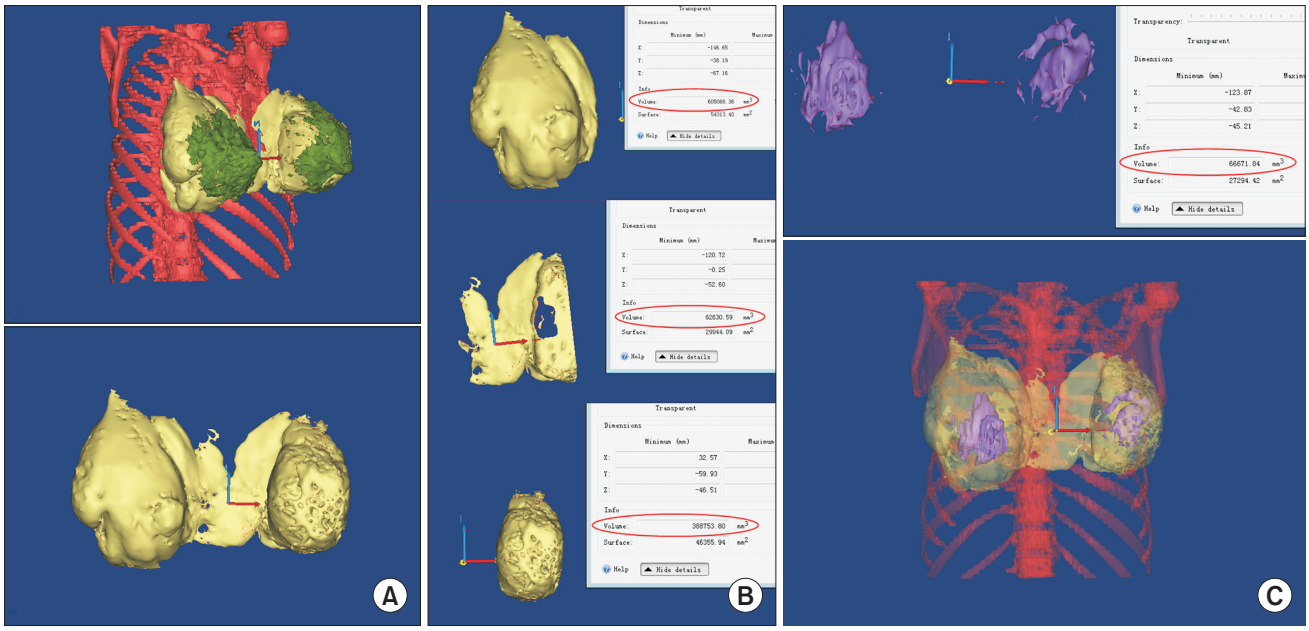

Fig. 3. The volume of polyacrylamide hydrogel (PAHG) was calculated through the three-dimensional (3D) reconstruction of MRI by Mimics software (Materialise Co.). (A) Upper panel: the 3D reconstruction of the PAHG with the mammary gland tissue and the costal bones preoperatively, which could facilitate the investigation of the location of the PAHG (yellow color, PAHG; green color, mammary gland tissue; and red color, costal bones). Lower panel: the 3D reconstruction of the PAHG preoperatively by importing the DICOM (Digital Imaging and Communications in Medicine) images of the MRI into Mimics software. (B) The preoperative volume of PAHG was calculated by the Mimics software (red circle, the volume of the different parts of the PAHG of bilateral breasts). (C) Upper panel: the postoperative volume of PAHG was calculated by the Mimics software (red circle, the volume of the PAHG of bilateral breasts). Lower panel: the 3D reconstruction of PAHG comparison between preoperation and postoperation (yellow color, PAHG preoperation; purple color, PAHG postoperation; and red color, costal bones).

Twenty-two patients had received evacuation surgery in other hospitals previously, 3 of which received evacuation surgery in our department for only 1 side. Among these 22 patients, 7 patients sought medical advice in our hospital due to distending pain discomfort, and 13 patients underwent secondary surgery to remove residual PAHG due to psychological reasons. Five patients underwent the inframammary fold approach, and the others had semi-periareolar incisions. Thirty-three patients (16.2%) received the PAHG removal only, additional capsule removal was performed in 134 patients (65.7%), and 37 patients (18.1%) were provided additional removal of capsule and infiltrating tissue. After identification, the injected materials samples were considered to have no bacterial growth. Tissue fibrosis, foreign body reaction, chronic inflammatory response, tissue inactivation, and small vessel degeneration were found by pathological examination of the removed tissues. The combined surgery included breast augmentation with an implant for 10 patients, and mastopexy for 3 patients. No other complications like hematoma or wound healing abnormality were observed. One patient had a clinical capsular contraction with the Baker classification III, who received the repair surgery. And one patient was provided secondary surgery for intermuscular PAHG residue (Table 2).

Table 1. Demographic data of patients undergoing PAHG evacuation with the assistance of MRI and color Doppler ultrasound

Characteristic	Data
No. of patients	204
Age (yr)	42.8 ± 8.6
Body mass index (kg/m^2)	21.2 ± 2.0
Time of PAHG injected (yr)	13.5 ± 3.9
Location of PAHG	
Subglandular + intra- and submuscular	67 (32.8)
Subglandular	60 (29.4)
Subglandular + subcutaneous	35 (17.2)
Subglandular + subcutaneous + intra- and submuscular	35 (17.2)
Intra- and submuscular	7 (3.4)
Reasons for the PAHG removal surgery	
Anxiety while absence of symptoms	81 (39.7)
Distending pain discomfort	69 (33.8)
Indurations	45 (22.1)
Injection displacement	19 (9.3)
Complaints of residue of PAHG	5 (2.5)

Values are presented as number only, mean ± standard deviation, or number (%).
PAAG, polyacrylamide hydrogel.

Table 2. Clinical data during the perioperative period of PAHG evacuation

Category	Data (n = 204)
Received evacuation surgery before	
Yes	22 (10.8)
No	182 (89.2)
Received PAHG removal for only one side	
Yes	3 (1.5)
No	201 (98.5)
Surgery approach	
Semi-periareolar	199 (97.5)
Inframammary fold	5 (2.5)
Procedures of the surgery	
PAHG removal	33 (16.2)
PAHG removal + capsule removal	134 (65.7)
PAHG removal + capsule and infiltrating tissue removal	37 (18.1)
Combined surgery	
Breast augmentation with implant	10 (4.9)
Mastopexy	3 (1.5)
Complications	
Capsular contraction (n = 10)	1 (10.0)
PAHG residue	1 (0.5)

Values are presented as number (%).
PAAG, polyacrylamide hydrogel.

Fifty-two patients received the MR scan both pre- and postoperation of PAHG removal, and the 3D volume of PAHG was calculated through reconstruction by Mimics software. The mean 3D volume of PAHG injected for breast augmentation was 684.8 mL (range, 350.0–1,123.9 mL), and the average residual 3D volume of PAHG postoperation was 53.7 mL (range, 12.4–98.3 mL). The mean clearance rate was 92.1% (range, 85.6%–97.0%).

DISCUSSION

The mobility of hydrogel along the intermuscular gap has been confirmed in animal experiments [8]. This trait causes irregular distribution of PAHG, which makes it complex to be removed. For the patients provided multilevel, scattered, and multipoint injections, the infiltration into the muscle and subcutaneous tissue is commonly observed, which makes it extremely difficult to completely remove the injected material from the breasts. Reports on the application of MRI or color Doppler ultrasound alone for PAHG localization have been published by other clinical research centers [8,10]. In order to localize PAHG accurately, our center applies both MRI and color Doppler ultrasound to provide a more precise localization for the procedure. The results of this study showed that the application of MRI combined with intraoperative color Doppler ultrasound for PAHG localization can assist in the surgical evacuation of PAHG to a great extent up to 92.1% (range, 85.6%–97.0%) on the clearance rate.

The significance of MRI is well-recognized in the industry. Because of the high sensitivity, it can be a key step in the procedure of PAHG evacuation [1]. The principle of PAHG localization lies in the fact that PAHG is a kind of water-soluble substance, which exhibits a bright high signal in the T2-weighted imaging and contrasts strongly with the surrounding tissue. Therefore, MRI can reveal PAHG distribution accurately and be guidance for evacuation surgery. However, MRI also has its limitations. Firstly, the patients are in the prone position during the MR scan, which is different from the supine position during the surgery. Due to the soft and mobile nature of the breast, the inconsistent position between the examination and the actual state in surgery can result in systematic errors in judging the distribution of PAHG. Secondly, MRI transmits the location information through film and does not allow for intraoperative localization in real surgery time. Although the location information of PAHG provided by MRI is objective and accurate, there is a lack of carriers that can transmit the location information from MRI to surgical procedures. Therefore, there is a disconnection between the 2 processes, and errors in the PAHG location are inevitable. As mentioned above, in practice, the location information of PAHG through MRI only ensures approximate accuracy. Therefore, the application of MRI facilitates the localization of PAHG in patients who were injected in a single level, and whose PAHG concentrated without displacement. With the location information provided by MRI, the main cystic cavity where PAHG is concentrated can be found and removed easily.

In some cases, MRI is not able to meet our requirement of removing as much PAHG as possible. As far as we are concerned, the efficiency of the MRI was limited by the following situations: level disordered of injection, scattered distribution of PAHG, and distant displacement of PAHG. For these patients, approximate accurate location information provided by MRI does not work due to the scattered presence of multiple cavities filled with injected materials. In this case, intraoperative color Doppler ultrasound can be used during the surgery to be a guidance for localizing PAHG cavities.

Color Doppler ultrasound has its own irreplaceable characteristics. First of all, it can visualize the superficial soft tissues and localize the injected PAHG precisely [6]. According to the sonographic images, PAHG is characterized as anechoic and hypoechoic areas at 1 or more tissue planes, which vary in extent and size. Secondly, color Doppler ultrasound is a real-time examination method. The range of examination can be expanded whenever needed during the surgery. The tissue under the probe can be instantly displayed on the screen with its aid. All the superficial soft tissue of the breast including skin, subcutaneous breast parenchyma, and the distribution of PAHG can be clearly displayed. This can precisely reveal the

anatomical plane of the PAHG cysts to improve the efficiency of PAHG removal. In addition, the patient's position during the intraoperative color Doppler ultrasonography is the same as the position during the surgery. Therefore, the location information of PAHG obtained by the intraoperative color Doppler ultrasonography is accurate and referable. Thus, in contrast to MRI, the location information showed by intraoperative color Doppler ultrasonography is not affected by the soft and fluid nature of the breast. Thirdly, as a small-size machine, color Doppler ultrasound is easily accessible. Besides that, it is a convenient and non-invasive method for PAHG localization. Although intraoperative ultrasound has numerous advantages mentioned above, there are still some limitations in localizing PAHG cysts. Its ability to visualize deep tissues such as the pectoralis muscle and posterior pectoral space is poor, and it can only provide planar images. MRI can be a good remedy for these problems, because it provides a good visualization of the deep tissue and offers a clear distribution of PAHG and the stereological structure in relation to the surrounding tissue.

In brief, there is no doubt that in order to localize PAHG exactly and help the patients who were injected PAHG for breast augmentation, to maximize the clearance rate, combining the application of MRI and intraoperative ultrasound is a better choice.

In order to evaluate the PAHG removal rate objectively, our clinical research center quantified the degree of PAHG removal for the first time to the best of our knowledge. A report on preoperative measurement of PAHG volume has been published previously [10]. However, due to the water-soluble characteristics of PAHG, some of the material was removed by irrigating with saline repeatedly. Besides this, not only the PAHG but also the capsule and degenerated tissue must be removed during the operation. Therefore, there is no comparison between the actual volume of removed PAHG and the volume calculated preoperatively based on MRI. The patients in this study were also scheduled for postoperative MR scans, and then PAHG residuals were calculated in the same way. It is worth mentioning that to compare the statistical difference of PAHG volume pre- and postoperation, the 3D reconstruction of MRI is a useful way to evaluate the efficiency of PAHG removal objectively.

There were still some limitations to this study. First, it was a single-institution retrospective study without a control group, which had limited evidence to indicate that clearance rates used MRI and ultrasound were higher than that when a single method (MRI or ultrasound) was used. Second, the sample size of this research was still small and only included asymptomatic patients. This could potentially impact the generalizability of the results. Therefore, further studies involving a larger number of patients whether symptomatic or asymptomatic are needed to evaluate the effectiveness of this method. More multicenter, randomized controlled trials should be conducted, which include more patients who underwent evacuation surgery after PAHG injection for breast augmentation, to further investigate the usefulness of the combination of MRI and ultrasound in PAHG evacuation surgery.

In conclusion, medical imaging technology can provide surgeons with objective and accurate localization information of PAHG in patients who have received PAHG injections for breast augmentation. MRI and color Doppler ultrasound have complementary advantages and can provide reliable localization information for PAHG removal, and merely via this approach can we obtain better results of clearance rate.

SUPPLEMENTARY MATERIALS

Supplementary Video 1 can be found via https://doi.org/10.4174/astr.2024.106.1.31.

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Methodology: YCX, BL
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