Literature Review

Review of the Safety of Bipolar Radiofrequency Ablation in Patients with Chronic Pain with Implantable Cardiac Rhythm Management Devices

Rewais Hanna, BS, and Alaa Abd-Elsayed, MD

From: Department of Anesthesiology, University of Wisconsin School of Medicine and Public Health, Madison, WI

Address Correspondence:
Alaa Abd-Elsayed, MD
Department of Anesthesiology
University of Wisconsin School of Medicine and Public Health
600 Highland Ave., B6/319 CSC
Madison, WI 53792-3272
E-mail: alaaawny@hotmail.com

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Background: Chronic pain, especially low back pain and hip pain, has been a growing public health concern that affects over 100 million Americans annually. Radiofrequency ablation (RFA) has distinct advantages over other chronic pain management modalities and its use has been increasing over the past decade. Among the growing population with comorbid conduction disorders and persistent pain, RFA and its potential interference with implantable cardiac devices is of concern.

RFA is becoming a foundational element of persistent pain management and has been shown to be effective in a multitude of chronic pain syndromes. Cardiac implantable electronic devices (CIED), such as cardiac pacemakers or implantable cardioverter defibrillators, have been used in the treatment of cardiac conduction diseases for a number of decades. With our aging population, these diseases have increased in both incidence and prevalence. Chronic pain and cardiac conduction diseases are both common in our increasingly aging population.

Objectives: This study aims to determine if the literature supports the hypothesis that patients with CIEDs can safely use RFA with minimal to no interaction.

Study Design: Systematic assessment of literature with a modified approach with bipolar RFA.

Methods: A narrative review with systematic assessment of the literature was carried out. In this review, we included randomized controlled trials (RCTs), open non-randomized control studies, prospective studies, retrospective studies, case series, and case reports. All types of radiofrequency utilized for pain management including pulsed and conventional were included. Outcome measures included interactions between the cardiovascular implantable electronic device (CIED) and radiofrequency ablation (RFA), adverse events, RFA efficacy in treating the pain using pain scores, and other complications.

Results: Our search criteria yielded 4 studies for inclusion, with inclusion of 33 patients and 71 bipolar radiofrequency for treatments. No adverse events or interactions occurred between the bipolar radiofrequency device and the implanted cardiac devices in any of these patients. Bipolar radiofrequency was utilized in all patients (n = 33). Overall there were no complications or malfunctions.

Limitations: Small sample size, narrative review.

Conclusions: This study provides evidence that bipolar RFA can be safely used in patients with CIEDs for chronic pain provided that proper precautions are employed. Considerations for safe use are provided.

Key words: Chronic pain, CIED, radiofrequency ablation

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Chronic pain impacts over 100 million Americans, often elderly, annually. Total health care cost estimates have ranged from $560 to $635 billion dollars annually mainly due to lost productivity and reduced wages (1). Low back pain, one of the most common forms of chronic pain, is experienced by over 80% of the global population and is responsible for over $100 billion in costs yearly (2). Over the past several decades, there have been substantial advances in pain management including radiofrequency ablation (RFA) treatment.

RFA has long been used effectively to treat chronic pain and numerous types of cardiac arrhythmias, among other uses, for over 40 years. Recently, RFA has become a mainstay in persistent pain treatment. It uses an insulated needle to deliver high-frequency electrical current

that produces thermal energy to create a lesion within the nerve, disrupting the pain signal from that nerve (3). In 2014, Leggett et al (4) performed a systematic review and concluded RFA is effective in treating lumbar facet joint and sacroiliac joint pain, 2 of the most common regions for persistent pain. Additionally, RFA has promising results in regard to osteoarthritic knee pain. Of the American population, 37% have radiographic evidence of osteoarthritic changes of the knee and 12% have knee pain related to arthritis (5). Our group previously performed a systematic review suggesting both short- and long-term improvement in analgesia following RFA of the knee (6). Moreover, RFA has been successfully used for other chronic pain syndromes including radicular pain, sacroiliac joint pain, postsurgical pain, shoulder pain, and myofascial pain (7-10). Furthermore, RFA has numerous advantages over conventional pain-relieving treatments. It is an ideal alternative for nonsurgical candidates, patients who have failed conventional treatment, or those who are not indicated for corticosteroid injections. Other benefits include the ability to be repeated as needed (11) and noninvasive nature.

Cardiac implantable electronic devices (CIED), which include devices such as pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and implanted rhythm monitors, have been the foundation of treatment of cardiac conduction diseases for numerous decades. With the aging population, these diseases have increased in both incidence and prevalence (12). The use of CIEDs have significantly increased as access, monitoring, and technologies have improved, and indications have expanded.

Furthermore, the elderly population in the United States often have comorbid cardiac conduction disease and chronic pain (13). The use of RFA and CIEDs concurrently are potentially concerning due to electromagnetic interaction (EMI). When 2 electrical or magnetic fields interfere, EMI occurs. An electrical field is an area where electrical charges are present, and a magnetic field is formed when electrical current flows in a conductor with magnetic field lines perpendicular to the current flow (14). Consequently, EMI is most notably affected by distance and position, the intensity and frequency spectrum of the electromagnetic field, duration of exposure, and lead configuration of the electrical source (15). Minimizing these variables is paramount in reducing EMI.

The purpose of this study was to systematically review the interactions between RFA specifically for treating chronic pain and CIEDs. Our central hypothesis was that RFA for chronic pain is safe and will not interfere with the electromagnetic signals of implantable cardiac devices. This review aims to determine if literature provides evidence that RFA in chronic pain is safe in patients with implantable devices, such permanent heart pacemakers (PPMs), ICDs, and CRT.

Methods

A systematic review was performed. Medline, PubMed, Cochrane Database of Systematic Reviews, PROSPERO, and Cochrane Central Register of Controlled Trials was searched for relevant literature concerning our hypothesis and research question. The following MeSH terms: "radiofrequency ablation," "radiofrequency," "RF," "ablation," "neurolysis," "pulsed radiofrequency," "radiofrequency therapy," "cardiac implant," "pacemaker," "cardiac pacemaker," "atrio-biventricular pacing," "biventricular pacing," "cardiac resynchronization," "cardiac resynchronization pacing therapy," "defibrillator," "automated external defibrillators," "defibrillators, external," "electric shock cardiac stimulators," "stimulators," "electrical cardiac," "stimulators, electrical, cardiac, shock," "cardiovascular implantable electronic devices," and "CIED" were used as inclusion literature.

Additionally, a systematic review was performed to make recommendations regarding safe extracardiac radiofrequency (RF) use and implantable cardiac devices using PubMed and Cochrane Databases. The following MeSH terms "radiofrequency ablation," "radiofrequency," "RF," "perioperative management," "recommendations," "extra-cardiac," "pacemaker," and "cardiovascular implantable electronic devices," were used as inclusion literature. These studies were reviewed for recommendations or guidelines regarding the use of RF in patients with CIEDs.

We included randomized controlled trials, open nonrandomized control studies, prospective studies, retrospective studies, case series, and case reports for our systematic review. All types of RFA, including pulsed and conventional, were included as long as they were used to treat pain. The exclusion criteria included articles not in English, animal studies, non-RFAs, RFA not used to treat pain, and other types of catheter ablations.

Outcome measures included interactions between the CIED and RFA, adverse events, RFA efficacy in treating the pain using pain scores, and other complications.

Results

Our results relating to RFA for treating pain and its interaction with implantable cardiac devices yielded 4 studies (Table 1). Our initial results yielded 66 studies

Table 1. *RF used for pain and its interaction with CIEDs.*

Study	Method	Patient Population	Interventions	Outcomes	Results	Conclusions
Bautista et al. "Bipolar radiofrequency neurotomy to treat neck and back pain in patients with automatic implantable cardioverter defibrillator" (16)	Case study	2 patients with complex cardiac histories and AICD devices	Treated with bipolar RFA of the facet joints	Pain score and functionality	No evident complications related to AICD devices. Both patients reported more than 50% sustained pain relief and improvement in their functionality	"2 cases of patients with AICD who found relief from their facetogenic pain through bipolar RF lesioning of the medial branch nerves without any complications in relation to AICD"
Barbieri and Bellini. "Radiofrequency neurotomy for the treatment of chronic pain: interference with implantable medical devices"(17)	Retrospective study	30 patients with implanted medical devices (5 ICD, 5 PM)	Underwent 68 treatments consisting of radiofrequency neurotomy of the lumbar facet joints, intervertebral discs, sacroiliac joint, and peripheral nerves	The patients' ECGs were monitored before, during, and after the procedure. Also stimulus frequency, pulse duration, intensity of stimulus, interelectrode impedances, and electrode configuration were recorded	No adverse reactions were recorded due to electrical interaction or due to clinical events. Implantable cardioverter defibrillator and pacemaker activity did not suffer any interference. No differences in neurological or cardiac examination after the treatment were reported.	"Results suggest that the RF intervention can be safely applied to patients carrying electrical devices"
Sun et al. "Percutaneous radiofrequency trigeminal rhizotomy in a patient with an implanted cardiac pacemaker" (18)	Case study	1 patient who presented with a cardiac pacemaker and a 30-yr history of right-sided trigeminal neuralgia not responding to medical therapy	Percutaneous radiofrequency trigeminal rhizotomy	Interaction between RFA and implanted cardiac pacemaker	During the stimulation and the RFA, the usual radiofrequency artifact in the ECG was noted, but the pacemaker output remained continuous, as evidenced by the peripheral pulse waveform on the pulse oximeter plethysmograph; the procedure was completed uneventfully. The patient remained stable throughout. Postoperatively, the pacemaker was interrogated, showing no change in its variables	"First reported case of percutaneous radiofrequency of the trigeminal nerve in patient with an implanted cardiac pulse generator with no complications"
Smith et al. "Radiofrequency neurotomy for facet joint pain in patients with permanent pacemakers and defibrillators" (19)	Expert review	N/A	N/A	N/A	N/A	"There are no known reports of radiofrequency neurotomy procedures for spine or other joint pain causing ICD/ pacemaker dysfunction that led to serious injury or death. However, caution is advised in patients who have cardiac pacemakers and defibrillators. If a decision is made to proceed with RFN in these patients, physicians should consider precautions"

Abbreviations: ECG, electrocardiogram; N/A, not available; PM, pacemaker; RFA, radiofrequency ablation; AICD: automatic implantable cardioverter-defibrillator; ICD: implantable cardioverter defbrillator; RFN: radiofrequency neurotomy.

(Fig. 1), of which 62 were excluded due to RFA use not related to pain, leaving 4 studies to be included in our systematic review. There is a paucity of data related to RFA specifically used for pain and its interference with implantable cardiac devices. As further detailed in Table 1, one retrospective study, 2 case reports, and one expert review were included.

In the included studies, 33 patients and 71 bipolar RF treatments were assessed. No adverse events or interactions occurred between the RF device and the implanted cardiac devices in any of these patients. Seven automated implantable cardioverter defibrillator (AICD) devices and 6 pacemakers were included in this review. Additionally, Bautista et al (16) reported a 50% increase in reported facetogenic pain relief and functionality 1 month post-RF treatment. They also noted no complications or malfunction with both patients' AICD devices 1 month posttreatment. Barbieri and Bellini (17) and Sun et al (18) reported similar findings in their studies. Electrocardiograms (ECGs) pre-, during, and posttreatments showed no change in cardiac electrical conduction or changes to implanted cardiac devices' internal variables.

Discussion

RFA has been shown to effectively reduce pain in lumbar facet joint and sacroiliac joint pain, knee, shoulder, trigeminal neuralgia, and radicular pain (1-5). Several reviews have shown it to be safe and effective in patients with cardiac implantable electronic devices (CIED) (19-25). Moreover, patients with pain from the lumbar zygapophysial joints noted a significant improvement in pain symptoms, quality of life variables, global perception of improvement, and quality of life 6 months following RFA (26). Furthermore, RF has a 1.0% incidence of side effects, most notably cases of localized pain and neuritic pain (27). This study also found that no cases of infection, new motor deficits, or new sensory deficits were identified (27). With significant benefits and limited side effects, RF has promise in chronic pain management. To our knowledge, this is the first study to systematically review its interactions with ICDs specifically in use for treatment of pain.

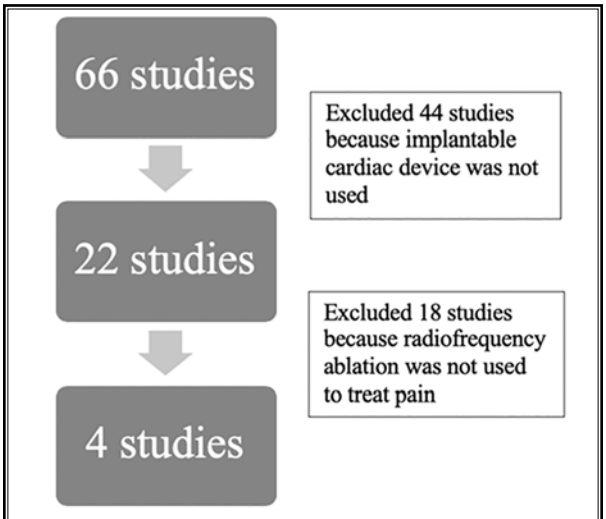

Fig. 1. *Flow chart of included and excluded studies.*

Pain physicians have long been interested in the interactions between CIEDs and RFA. EMI is a significant safety concern in surgical patients with an ICD (23). Previously, numerous studies have reported EMI between RF waves and CIEDs. This interference can cause inappropriate pacing, inappropriate inhibition, delivering a countershock, loss of lead integrity, pacing generation failure, malfunction thermal burns at the lead–tissue interface that can raise the pacing threshold, and inappropriate anti-tachycardia therapy, among other complications (20-22). Unipolar pacemaker leads have also been shown to be particularly susceptible to EMI (16,21).

A limitation of this study was the limited sample size (n = 33), preventing the absolute conclusion that there is no risk of interference between CIEDs and bipolar RFA. This present study provides evidence in a limited sample size that RF has been safely used to treat pain in patients with CIEDs with proper precautions. This work warrants additional research utilizing these theoretical precautions and testing their safety and efficacy in patients with chronic pain and CIEDs in a larger sample size.

Considerations

By systematically reviewing the interaction between RF and CIEDs, we summarize the following guidelines. Using the studies listed in Table 2, we propose the following guidelines for safe RF use for extracardiac pain syndromes in patients with CIEDs:

1. Thorough communication between pain physician and treating cardiologist.
2. Consider having cardiac device manufacturer support prepared onsite during the procedure for potential reprogramming if needed.
3. Implantable cardiac device should be interrogated prior to and after RF procedure.
4. Keep RF application as brief as possible.
5. RF application should be as remote as possible from CIED (5 cm or more).

Table 2. *Extra cardiac recommendations for safe RF use in patients with ICDs.*

Study	Recommendations
Bautista et al. "Bipolar radiofrequency neurotomy to treat neck and back pain in patients with automatic implantable cardioverter defibrillator" (16)	"We propose the use of bipolar RF (rather than monopolar RF) in patients with facetogenic pain. The theoretical explanation for the use of bipolar RF involves the flow of current between the forceps of the tool. Current passes from the active electrode at one tip through the patient (but only at the diathermy site) to the dispersive electrode at the other forceps tip. A regional electromagnetic field of low intensity results in the direct area of intervention. Therefore, the theoretical risk of EMI associated with bipolar is substantially less than with monopolar RF."
Barbieri and Bellini. "Radiofrequency neurotomy for the treatment of chronic pain: Interference with implantable medical devices" (17)	"RF applications should be as brief as possible and remote from the pacing electrode tip. Re-interrogation of the device after the procedure is essential and integrity of the circuit should be evaluated. In particular for a pacemaker, rate response function should be turned off. If a patient is not dependent, the pacemaker can be programmed to DDI or VVI at a lower rate than the intrinsic heart rate. If the patient is dependent, the PM should be programmed to VOO or DOO mode and a temporary PM wire should be in place as back-up. ECGs must be monitored before, during, and after the procedure. For ICDs, the potential interactions are asynchronous pacing, inhibition of pacing, inappropriate shock therapy, and changes in pacing thresholds. To mitigate the possible interaction, deactivate anti-tachytherapy, program the device Tachy Mode to 'off' and the pacing mode switches to VOO, AOO, or DOO."
Sun et al. "Percutaneous radiofrequency trigeminal rhizotomy in a patient with an implanted cardiac pacemaker" (18)	"Rate responsive modes should be turned off and consideration given to reprogramming the pacemaker to an asynchronous mode before surgery, particularly if the patient is pacemaker-dependent. Our patient was not put into asynchronous mode because the pacemaker clinic assumed this mode was not available on this older generation pacemaker. (This was erroneous information, and he probably would be placed in VOO mode if he presented again). An alternative means of pacing should be available. The use of magnets is no longer recommended to protect the pulse generator from EMI because the magnet response will vary depending on the pacemaker design, programming, and battery voltage. Other measures include placing the rhizotomy current receiving plate away from the pacemaker. This reduces the opportunity for current to be conducted through the pacemaker and lead system as it flows from the needle electrode to the RFA receiving plate."
Donnelly et al. "Perioperative management of patients with implantable cardioverter defibrillators" (23)	"Establish the device manufacturer and program from the patient-held card, arrange interrogation of the ICD, if not performed within the last six months. If diathermy will be required, reprogram the ICD pre-operatively to monitor mode. Bipolar diathermy is preferred, and low energy short bursts are desirable. If monopolar diathermy is essential, low energy, short bursts are preferred. Diathermy cables and the grounding electrode should be remote from the ICD. Arrange for ICD interrogation post-operatively"
Chin et al. "The effect of radiofrequency catheter ablation on permanent pacemakers: An experimental study" (24)	"We propose the following guidelines for radiofrequency catheter ablation in patients with a permanent pacing system: (1) Temporary external sources of pacing should be available during radiofrequency ablation as a standby should the permanent system be inhibited; (2) Because of the risk of pacemaker runaway, pacing systems should be temporarily reprogrammed to minimum output or to the OOO mode if available; (3) A complete pacing system analysis should be performed following ablation in all patients; and (4) particular caution should be exercised during radiofrequency ablation in close proximity to the atrial or ventricular permanent pacing leads."
Hayes et al. "Radiofrequency treatment of hepatic neoplasms in patients with permanent pacemakers" (25)	"Precautions used included programming to the VOO pacing mode, having a programmer present and "on," and having an external pacing system available and ready to be activated in the event of prolonged inhibition of the permanent pacemaker."
Beinart and Nazarian. "Effects of external electrical and magnetic fields on pacemakers and defibrillators: From engineering principles to clinical practice" (14)	"The perioperative management of CIEDs must be individualized to the patient, the type of CIEDs and the procedure being performed. All patients with pacemakers and ICDs undergoing elective surgery should have had a device check as part of routine care within the past 12 and 6 months, respectively. Maximize the distance between the electrosurgery current path and the CIED. Consider the use of bipolar cautery. Use the minimum power settings required for adequate electrosurgery. Using short bursts may also be required if inhibitions are observed. Emergency equipment should be easily accessible to the procedure area. External defibrillation equipment is required in the procedure room. All patients with pacemakers or ICDs require blood pressure monitoring for all surgical and sedation procedures. Use an ECG monitor with a pacing mode set to recognize pacing stimuli. Keep a magnet immediately available for all patients with CIEDs who are undergoing a procedure that may involve EMI. Turning off ICD arrhythmia detection (by programming or magnet application) is recommended for all procedures above the umbilicus that utilize monopolar electrosurgery or radiofrequency ablation. For procedures below the umbilicus pacemaker programming is typically unnecessary."

Table 2 con't. *Extra cardiac recommendations for safe RF use in patients with ICDs.*

Study	Recommendations
Smith et al. "Radiofrequency neurotomy for facet joint pain in patients with permanent pacemakers and defibrillators" (19)	"Educate the patient on the potential hazards and risks of RFN in the setting of a pre-existing PPM or ICD. Ensure the patient is followed by a cardiologist/electrophysiologist and obtain prior approval from the provider, which should be documented in the patient's medical record. Consider coordination of RFN procedure with the cardiac device manufacturer to have on-site support for interrogation of the cardiac device during the procedure in the event reprogramming of the device is required. Place a magnet over the device to inhibit triggering the device by RFN. Remove the magnet or use external defibrillator/pacing electrodes if cardiac arrhythmias occur during the RFN procedure."
"Radiofrequency ablation and implantable device systems – Boston Scientific" (28)	"Deactivate tachy therapy. Program the device Tachy Mode to Electrocautery Protection Mode or to Off- Electrocautery, if available. In this mode, tachy detection and therapy features are deactivated, and the pacing mode switches to VOO, AOO, or DOO or program the device Tachy Mode to Off or place a magnet over the device to temporarily inhibit or deactivate tachy therapy. The brady pacing mode remains as programmed. A magnet can be placed over the device to pace asynchronously at the magnet rate. The device can be programmed to an asynchronous mode (AOO/VOO/DOO). Monitor the patient and have temporary pacing equipment, external defibrillation equipment, and knowledgeable medical personnel available. Avoid direct contact between the ablation catheter and the implanted device and lead(s). Keep the current path (electrode tip to ground plate) as far away from the implanted device and lead(s) as possible. Consider the use of external pacing support for pacemaker-dependent patients (i.e., using internal or external support methods). Verify lead integrity by comparing pre- and post-ablation measurements for sensing threshold, pacing threshold, and impedance. If any programming changes were made, the pulse generator should be reprogrammed back to the desired settings following the procedure. Reactivate the Tachy Mode on ICDs and CRT-Ds."
Govekar et al. "Effect of monopolar radiofrequency energy on pacemaker function" (29)	"Lowering the generator power, using cut mode, using intermittent short bursts of the active electrode, and placing the dispersive electrode to avoid traversing of the generator by the current vector or leads all reduce pacemaker inhibition caused by monopolar instruments."
Tong et al. "Extracardiac radiofrequency ablation interferes with pacemaker function but does not damage the device" (30)	"We propose the following as precautions for extracardiac radiofrequency ablation in patients with a permanent pacing system: The distance between the extracardiac radiofrequency delivery system and the ventricular pacing lead must be 5 cm or more, depending on the power and treatment volume of the radiofrequency equipment used. Temporary external sources of pacing should be available as a standby, should the permanent system be inhibited. The generator should be examined before and after the procedure in case any changes occur that necessitate reprogramming"
American Society of Anesthesiologists. "Practice advisory for the perioperative management of patients with cardiac implantable electronic devices: Pacemakers and implantable cardioverter-defibrillators" (31)	"Management of potential sources of EMI associated with RF ablation primarily involves keeping the RF current path (electrode tip to current return pad) as far away from the pulse generator and lead system as possible. One observational study reports 3 of 12 cases that resulted in a significant drop in resistance on the pacemaker leads when RF ablation was used in proximity to the leads. One case report suggests that positioning of the RF ablation cluster electrode no closer than 5 cm from the pacer leads allowed the procedure to continue uneventfully. The majority of consultants, ASA members, and HRS members agree that the individual performing the procedure should avoid direct contact between the ablation catheter and the CIED and leads and should keep the RF ablation current path as far away from the pulse generator and lead system as possible."

Abbreviations: AOO, asynchronous atrial pacing; ASA, American Society of Anesthesiologists; CRT-D, cardiac resynchronization therapy defibrillator; DDI, dual-chamber antibradycardia pacing with atrial activity being tracked into the ventricle only when the atria is paced; DOO, asynchronous atrial+ventricular pacing; ECG, electrocardiogram; EMI, electromagnetic interaction; HRS, Heart Rhythm Society; OOO, Off Mode; PM, pacemaker; PPM, permanent pacemaker; RFN, radiofrequency neurotomy; VOO, asynchronous V pacing; VVI, single chamber ventricular pacemaker.

6. Keep the CIED generator away from the path between the needles and the grounding pad.
7. Turn rate response "OFF" on CIED if advised by cardiologist.
8. Have external source ready in case permanent system is inhibited during RF application and remove magnet over device if required.
9. Pacing system should temporarily be changed to minimum output or be placed in OOO (inhibitory) mode.
10. Have continuous ECG monitoring with a pacing mode to recognize pacing stimuli.
11. If any programming changes were made prior to the procedure, ensure they are returned back to the original program following RF application.
12. Ground pads should not be placed in a manner that crosses the path of the pacemaker. For example, when drawing a line between the needle and the grounding pad, it should be as far as possible from the pacemaker.

Conclusions

There is evidence that shows bipolar RFA for use in pain disorders can be performed with minimal risks in patients with implantable cardiac devices when proper precautions are utilized, including coordination with a patient's treating cardiologist and their specific device manufacturers.

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