Official Title:Comparison of Bolus Dosing of Methohexital and Propofol in Elective Direct Current Cardioversion
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Study Title: Comparison of bolus dosing of methohexital and propofol in elective DC cardioversion

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Background, Rationale and Context

Direct current cardioversion has been in clinical use since the 1960s for the treatment of both atrial fibrillation and atrial flutter to restore sinus rhythm.[1] By applying a QRS-synchronized current of energy through electrodes/pads placed on the chest wall, atrial arrhythmias can be reset and sinus rhythm restored. Direct current cardioversion (DCCV) is used in both a diagnostic and a therapeutic fashion in the management of atrial fibrillation (AF) and atrial flutter (AFL).[2] DCCV shocks are optimally delivered from electrodes in an anterior-posterior position, biphasic waveform, at high energy levels with a high acute success rate approaching 94-96%.[3,4] Due to the amount of energy applied to the chest, a DCCV can be an uncomfortable procedure for patients who are awake. To minimize the discomfort and pain, short acting, deep-sedation agents are used.[5] Different medication choices are available for sedation during this relatively brief procedure

Prior studies of deep sedation with anesthesia commonly compare propofol to other agents such as midazolam or etomidate. A recent review article evaluated randomized trials of the above medications concluded that propofol was the best option for use in DCCV when compared to the others.[6] The authors concluded that the hypotension and respiratory depression associated with propofol was acceptable when compared to the increased recovery time and risk of myoclonus of midazolam and etomidate, respectively.

At our institution, a majority of DCCV are performed in the electrophysiology lab (EP lab). Sedation is delivered by either a CRNA under the supervision of an anesthesiologist, or by an EP lab RN under the direction of an electrophysiologist. The medication choice for sedation has traditionally been at the discretion of the supervising physician. The medication choices for sedation at our institution have historically been either propofol or methohexital. Each medication has specific properties and pharmacokinetics that affect duration of action, hemodynamic changes, and respiratory depression.[7] Although these medications have been compared in other settings, such as during fracture and dislocation reduction in the ED,[8] there are limited studies on the use of methohexital for sedation during cardioversion. The largest study was a cost effectiveness cohort study of 1,473 patient undergoing an elective cardioversion using methohexital dosing of 0.4-0.6 mg/kg.[9] Although this was a cost effectiveness study, the safety and cost savings lead the authors to continue to use it for their cardioversions. To date there has been only one, small, randomized controlled trial comparing propofol and methohexital for DCCV.[10] There were only 10 patients per group in this three group randomized

controlled trial. Although it found no significant difference in the mean arterial pressure or time to awakening, there was a trend to quicker recovery in the patients receiving methohexital.

We intend to perform a randomized, open-blinded, prospective study to evaluate the timeliness and safety of DCCVs when using methohexital when compared to the more often used propofol. If there is a significant reduction in time to recovery from induction, the use of methohexital as compared to propofol can significantly decrease healthcare costs based on staff utilization and cost of medications.[10]

Objectives

Hypothesis:

We theorize that the use of methohexital during cardioversion will result in a shorter time to effective sedation and time to full recovery when compared to the use of propofol. This will change how sedation is approached for elective cardioversions.

Primary Hypothesis:

1. The mean time to recovery from sedation during a cardioversion using methohexital for sedation will be significantly shorter than the recovery time using propofol for sedation, as evidenced by a short time from initiation of induction to a score of 2 on the Ramsay Sedation Scale.
2. The mean time to a Ramsay score of 5-6 will be significantly shorter using methohexital than the time to the same sedation level using propofol

Secondary Hypothesis:

1. There will be no significant increase in adverse events associated with the use of methohexital when compared with propofol.

Methods and Measures

Design

We will perform a randomized, open-blinded, prospective study on all patients present for DCCV who meet inclusion criteria and consent to enrollment in the study. Patients will be randomized to sedation with bolus dosing of either propofol or methohexital

Setting

This will be a single site study at a large academic medical center – Wake Forest Baptist Medical Center

Subjects selection criteria

- **Inclusion Criteria**
  We will select all patients over the age of 18 who present to Wake Forest Baptist Medical Center for a direct current cardioversion for treatment of paroxysmal or persistent atrial fibrillation as well as atrial flutter.

- **Exclusion criteria**
  Patients with sedation for transesophageal echocardiogram within 30 minutes of DCCV will be excluded. Hemodynamically compromised patients (as defined by hypotension <90/50 mmHg, altered mental status, shock, ischemic chest discomfort, or heart failure) will also be excluded.

Sample Size

We intend to randomize a total of 150 patients to either propofol or methohexital

The following calculations have been used to establish the sample size for the full study

According to a study evaluating bolus dosing of propofol as outlined above, the time to recovery was 10.98 ± 2.51 min.[11]

We will presume that a significant difference in time to recovery will be 2 minutes based on the average recovery time of 9 minutes when using methohexital in a small randomized controlled trial utilizing bolus dosing.[12]

Estimated sample size for two-sample comparison of means
Null hypothesis: m1 = m2, where: m1 is the mean value in population 1
m2 is the mean value in population 2. Mean time to recovery from sedation with propofol is no different than mean time to recovery from sedation with methohexital.
Alternative hypothesis: m1 ≠ m2. Mean time to recovery from sedation with propofol is different than mean time to recovery from sedation with methohexital
Assumptions:
Alpha = 0.05 (two-sided)
Power = 0.8
Effect size = difference in mean value of the outcome variable population 1 and population 2 = 2 minutes
Standardized effect size = effect size ÷ standard deviation = 2 min ÷ 2.51 min = 0.797

Based on the above calculations we will need to review at least 50 patients in a 1:1 equal distribution between propofol and methohexital. We will randomize 150 patients to ensure significance.

Intervention and Interactions

All patients presenting to the EP lab will be informed about the study and those who agree to participate will sign informed consent.

Clinical data will be collected from electronic medical records of Wake Forest Baptist Health (WakeOne, Muse). Data that are not available electronically be obtained from the patient and/or accompanying

family members. The following clinical data will be collected: name, age, MRN, gender, ethnicity, race, height, weight, BMI, sodium, potassium, calcium, creatinine, creatinine clearance by Cockroft-Gault method, magnesium, presence or absence of antiarrhythmic medications (Na Channel blocker, Beta Blocker, Potassium Channel Blocker, Calcium Channel Blocker, Digoxin), CHA2DS2-VASC sore, HAS-BLED score, presence of Watchman device, type of anticoagulation, INR if on warfarin. In addition to this we will collect parameters from the most recent echocardiogram (<1 year): Left atrial (LA) diameter, LA volume index, LVEDV, LVESV, EF, presence of a pre-procedure TEE. We will include the following parameters from the clinical history: HTN, HFrEF (<50%), HFpEF (>50%), prior stroke, DM, COPD, thyroid disorder, smoking status, drinking history, ASA Status, and Arrhythmia type.[13,14]

Using the randomization tool within REDCap, our secure data storage program, stratified by sex, ASA status, and presence or absence of HFrEF (EF <50%), patients will be randomized to boluses of either methohexital or propofol. Methohexital will be given at an initial dose of 0.5 mg/kg, followed by 10 mg every minute after 2 minutes, if adequate sedation is not achieved. Propofol will be given at an initial dose of 0.8 mg/kg followed by 20 mg every minute after 2 minutes, if adequate sedation is not achieved.[9,15] The CRNA or anesthesiologist will draw up the pre-specified dose.

The modified Ramsay Sedation Scale (RSS) will be used to gage the level of sedation.[16] There are six sedation levels, three for awake and three for asleep. Awake levels are: 1, the patient is anxious, agitated or restless; 2, the patient is cooperative, oriented, and tranquil; 3, the patient responds to verbal commands. Asleep levels are: 4, the patient has a brisk response to a light glabellar tap or loud auditory stimulus; 5, sluggish response; 6, no response.

The goal level of sedation will be a Ramsay Sedation Scale (RSS) level of 5 or 6, as evidence by either sluggish or no response to a glabellar tap or loud auditory stimuli, respectively.[16] Due to differences in appearance of the medications (methohexital is clear, and propofol is milky), blinding of the administering personnel will prove to be difficult. Blinding of outcome assessment will be achieved by obscuring both the syringe and the patient's arm from the person collecting the information as well as the patient.[17] Data collection personnel will be equipped with a stopwatch as well as a laptop loaded with REDCap to effectively record all necessary predictor and outcome variables.

Baseline Oxygen supplementation at 4L by nasal cannula and saline administered via a peripheral IV will be available throughout the entire case. Self-adhesive pads will be placed in the antero-posterior position on the chest.[3] The patient will be given the prespecified dose of sedative. Once adequate sedation is achieved the patient will receive 100 to 150 J shock for atrial flutter and 150 to 200 J shock using a QRS synchronized biphasic defibrillator and self-adhesive pads (Zoll R-Series Plus and Pro-Padz, Zoll Medical Corporation, Chelmsford, MA, USA). The protocol will allow for a maximum of 3 shocks. If the initial attempt at DCCV is unsuccessful, manual pressure to the anterior pad will be allowed.

A standard 12-lead electrocardiogram (ECG) will be obtained before sedation, and after recovery. A 12-lead rhythm strip will be obtained roughly 10 seconds prior to DCCV and 20 seconds after each DCCV. All tracings will be acquired at a paper speed of 25 mm/s and a scale of 10 mm/mV (GE MAC55, GE Healthcare, Chicago, IL, USA). During the procedure, monitoring of heart rate (HR), brachial systolic

blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) respiratory rate (RR) and oxygen saturation (SpO2) will be measured through a mounted patient monitor (Phillips Intellivue MP5, Koninklijke Philips N.V, Amsterdam, Netherlands). The above parameters will be measured at induction, before the shock, and every minute after the shock for the first 10 minutes, 15 minutes, 20 minutes and 30 minutes.

The following time intervals for the procedure will be recorded in seconds: (T1) time from end of injection to loss of conscious [RSS 5-6]; (T2) Time to first shock; (T3) time to eyes opening [RSS 3]; (T4) Time the ability to answer simple questions of age and name [RSS 2]

Outcome Measures

The primary outcome to be measured will be (T4) the time from initiation of sedation to full recovery (RSS of 2) as evidenced by the ability to answer the questions "What is your name and what is your age?"[16] We will start the timer at the initiation of induction.

Secondary time based outcomes will include: (T1) time from end of injection to loss of conscious [RSS 5-6]; (T2) Time to first shock; (T3) time to eyes opening [RSS 3]. Secondary hemodynamic outcomes will be vital status parameters (HR, SBP, DBP, MAP, RR, SpO2) at induction, prior to first shock, then 1, 3, 5, 7, 9, 10, 15, 20, and 30 minutes after first cardioversion.

Procedural parameters measured will be: Number of DCCV, max energy used for successful DCCV, success of DCCV, dosage of medication (mg/kg), need for re-dosing.

Safety endpoints will be: evidence of bradycardia (HR <60 bpm), Hypotension (decrease in SBP ≥20%, hypoxemia (SpO2 nadir <85%), need for advanced airway maneuvers (jaw thrust/chin lift, or bag mask ventilation), apnea (respiratory arrest ≥ 20 seconds), Severity of World SIVA averse sedation event.[18]

Patient experience endpoints will be measured after full recovery: recall of pain at injection site (visual analog scale, VAS)[19], recall of anything unpleasant about the procedure (VAS). These are 100 mm lines that are anchored with "no pain" or "no distress" on one end and "worst imaginable pain" or "worst imaginable distress" on the other end. The patient will utilize the computerized VAS within REDCap to mark the appropriate level.

Variables

Predictor Variables: name, age, MRN, gender, ethnicity, race, height, weight, BMI, sodium, potassium, calcium, creatinine level, creatinine clearance, magnesium, CrCl by Cockcroft gault, presence or absence of antiarrhythmic medications (Na Channel blocker, Beta Blocker, Potassium Channel Blocker, Non-dihydropyridine CCB, digoxin), CHA_2DS_2-VASc score, HAS-BLED score, presence of Watchman, anticoagulation use: DOAC, Warfarin, ASA, Plavix, recent INR. Parameters from the most recent echocardiogram (<1 year): Left atrial (LA) diameter, LA volume index, LVEDV, LVESV, EF, pre-procedure TEE, Hypertension, congestive heart failure, stroke, diabetes, COPD, previous thyroid disorder, smoking status, alcohol use, ASA Status, Arrhythmia type (Atrial Fibrillation with RVR (HR >100 bpm), Atrial

Fibrillation with controlled VR (HR <100 bpm), Atrial Flutter with 2:1 block, Atrial Flutter with variable block), medication for sedation, final medication dose

Outcome variables: T1 time to LOC, T2 time to first shock, T3 time to eyes open, T4 time to recovery, HRinduction, HRshock, HR1, HR3, HR5, HR7, HR9, HR10, HR15, HR20, HR30, SBP (1,3…etc.), DBP (1,3…etc.), MAP (1,3…etc.), RR (1,3…etc.), SpO2 (1,3…etc.), NumCV, MaxEnergy, DCCVsuccess, MedDose(mg/kg), Redose,

Safety measures: Bradycardia, Hypotension, Vasopressor use, Hypoxemia, Jaw Thrust, Bag Mask, Invasive Airway, Apnea, SIVAseverity, PainVAS, UnpleasantVAS.

Analytical Plan

Continuous variables will be summarized with mean (standard deviation) or median (interquartile range) depending on the normality of the data and compared using student's t-test or Wilcoxon rank-sum test, respectively. Categorical variables will be summarized with counts (percent) and compared using chi-square tests. Multivariate linear regression analysis will be used to examine relationships further and adjust where necessary.

Potential Limitations:

Inability to double blind the treatment: due to the difference in appearance between methohexital (clear) and propofol (milky) we are unable to blind the administrator of the medication. However the researcher collecting the information and the patient will be blinded to treatment allocation by obscuring the patient's arm from the patient and the sedation type from the data collector. The selection of energy will be determined prior to randomization and selection for medication.

Lack of Generalizability: These findings will apply only to patients receiving DCCV as a separate procedure from a TEE. During a TEE/DCCV induction of anesthesia is initiated prior to the TEE, which can last 10-20 minutes, naturally lengthening the time from induction to full recovery. The lack of widespread acceptance of methohexital as an anesthetic agent in cardioversion may limit the adaptation of its future use as evidenced by claims in several recent review articles on sedation for DCCV.[6,20,21]

Expected Results:

We will identify all patients who present to the EP lab for DCCV with anesthesiology support. We expect a significant difference in the time to sedation and the recovery time after induction of anesthesia with methohexital compared to propofol. We also expect there to be less significant hemodynamic and respiratory side effects with the standard bolus dosing of methohexital vs propofol. If proven, our findings will validate the widespread use of methohexital as an agent of choice for sedation for cardioversions. The combination of the decreased per unit cost of methohexital and the potential of quicker recovery could lead to significant institutional savings.

Human Subjects Protection

Subject Recruitment Methods

Patients will be selected consecutively for participation as they present for loop implant or follow up in device clinic. They will be informed of the ongoing study and will then be given an informed consent form to sign. Participants will receive no compensation for participation in the study.

Informed Consent

Signed informed consent will be obtained from each subject. Consent will be obtained by the study coordinator, data collectors, and or the clinical investigators. This will occur in a quiet private holding area of the EP lab.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. Study data will be collected and managed using REDCap electronic data capture tools hosted at Wake Forest Baptist Health.[11] REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a separate master log. The master log will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed by deletion at the earliest opportunity, consistent with data validation and study design, producing an anonymous analytical data set. All paper collection tools will be deposited in locked recycling bins located in the Wake Forest Baptist Health Heart Station. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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Appendix

1. Inclusion/Exclusion Form
2. Demographics Form
3. Baseline Data Form
4. Randomization Form
5. Cardioversion Procedure Form
6. Cardioversion Workflow

Inclusion/Exclusion Form

Study ID _____

Inclusion Criteria

	Yes	No
Age > 18 years	◯	◯
Consent to cardioversion	◯	◯

If NO to any of the above, pt is to be withdrawn from the study

Exclusion Criteria

	Yes	No
Transesophageal Echo within the past 30 minutes	◯	◯
Severe hypotension present (SBP < 90 mmHg and/or DBP < 50 mmHg)	◯	◯
Altered Mental Status (Unable to answer correctly to name and place)	◯	◯
Ischemic Chest Discomfort	◯	◯
Decompensated heart failure (Volume overload by exam)	◯	◯

If YES to any of the above, pt is to be withdrawn from the study

Patient Withdrawn From Study
◯ Yes
◯ No

Demographics

Study ID

_____

Consent Information

Date subject signed consent

_____
(YYYY-MM-DD)

Contact Information

First Name

_____

Last Name

_____

Age

_____

MRN

_____

Gender

◯ Female
◯ Male

Ethnicity

◯ Hispanic or Latino ◯ NOT Hispanic or Latino ◯ Unknown / Not Reported

Race

◯ American Indian/Alaska Native
◯ Asian
◯ Native Hawaiian or Other Pacific Islander
◯ Black or African American
◯ White
◯ More Than One Race
◯ Unknown / Not Reported

Height

_____
(*.*** in meters (m))

Weight

_____
(***.* in kilograms (kg))

BMI

_____

Labs and Medications

Sodium

_____

Potassium

_____

Calcium

_____

Creatinine

_____

Creatinine Clearance

_____
(Cockroft-Gault)

Magnesium

_____

Taking Antiarrhythmic Drugs

◯ Yes
◯ No

If the patient answered yes to taking antiarrhythmics, which class of antiarrhythmics were taken

	Yes	No
Sodium Channel Blocker	☐	☐
Beta Blocker	☐	☐
Potassium Channel Blocker	☐	☐
Non-Dihydropyridine Calcium Channel Blocker	☐	☐
Digoxin	☐	☐

CHA2DS2-VASC Score

_____
(must calculate and input)

HAS-BLED Score

_____

Watchman Device?

◯ Yes
◯ No

Anticoagulation

◯ Direct oral anticoagulant
◯ Warfarin
◯ ASA
◯ ASA/Plavix
◯ Plavix
◯ none

INR

_____
(If on coumadin what is INR)

Baseline Data

Study ID

_____

Echocardiogram Results

Date of Echo

_____

Left Atrial Diameter (cm)

_____

LA Volume Index (ml/m2)

_____
(**.*)

LVEDV (MOD-sp2) (ml)

_____
(***.*)

LVESV (MOD-sp2) (ml)

_____
(***.*)

Ejection Fraction (%)

_____
(Use highest number)

Pre-Procedure TEE

◯ Yes
◯ No
(must have been >30 min pre DCCV)

Clinical History

HTN

◯ Yes
◯ No
(HTN or on meds for HTN)

HFrEF

◯ Yes
◯ No
(EF < 50%)

HFpEF

◯ Yes
◯ No
(EF > 50%)

Prior Stroke

◯ Yes
◯ No

Diabetes

◯ Yes
◯ No

COPD

◯ Yes
◯ No

Thyroid Disorder	◯ Yes ◯ No
Do you currently smoke tobacco products?	◯ Yes ◯ No
During the last 12 months, how often did you usually have any kind of drink containing alcohol? By a drink we mean half an ounce of absolute alcohol (e.g. a 12 ounce can or glass of beer or cooler, a 5 ounce glass of wine, or a drink containing 1 shot of liquor). Choose only one.	◯ Every day ◯ 5 - 6 times a week ◯ 3 - 4 times a week ◯ twice a week ◯ once a week ◯ 2 - 3 times a month ◯ once a month ◯ 3 - 11 times in the past year ◯ 1 or 2 times in the past year ◯ I did not drink any alcohol in the past year, but I did drink in the past ◯ I never drank any alcohol in my life
During the last 12 months, how many alcoholic drinks did you have on a typical day when you drank alcohol?	◯ 25 or more drinks ◯ 19 to 24 drinks ◯ 16 to 18 drinks ◯ 12 to 15 drinks ◯ 9 to 11 drinks ◯ 7 to 8 drinks ◯ 5 to 6 drinks ◯ 3 to 4 drinks ◯ 2 drinks ◯ 1 drink
During the last 12 months, what is the largest number of drinks containing alcohol that you drank within a 24-hour period?	◯ 36 drinks or more ◯ 24 to 35 drinks ◯ 18 to 23 drinks ◯ 12 to 17 drinks ◯ 8 to 11 drinks ◯ 5 to 7 drinks ◯ 4 drinks ◯ 3 drinks ◯ 2 drinks ◯ 1 drink
During the last 12 months, how often did you have 5 or more (males) or 4 or more (females) drinks containing any kind of alcohol in within a two-hour period? [That would be the equivalent of at least 5 (4) 12-ounce cans or bottles of beer, 5 (4) five ounce glasses of wine, 5 (4) drinks each containing one shot of liquor or spirits - to be provided by interviewer if asked.] Choose only one.	◯ Every day ◯ 5 to 6 days a week ◯ 3 to 4 days a week ◯ two days a week ◯ one day a week ◯ 2 to 3 days a month ◯ one day a month ◯ 3 to 11 days in the past year ◯ 1 or 2 days in the past year

ASA Status	◯ ASA I Normal Healthy Patient: Healthy, non-smoking, no or minimal alcohol use ◯ ASA II Mild Systemic Disease: Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease ◯ ASA III Severe Systemic Disease: Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity(BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI,CVA, TIA, or CAD/stents ◯ ASA IV Severe Systemic Disease That Is A Constant Threat To Life: Examples include (but not limited to): recent (< 3months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
Arrhythmia Type	◯ Atrial Fibrillation with RVR (HR>100 bpm) ◯ Atrial Fibrillation with controlled VR (HR < 100 bpm) ◯ Atrial Flutter with 2:1 Block ◯ Atrial Flutter with variable block

Randomization Form

Study ID _____

Randomization Form: To be filled out by Anesthesiology, Data Collector To be Blinded

Randomization Group
◯ Methohexital
◯ Propofol

Total Dose Given (mg) _____

Total Dose per body weight _____

Extra Dosing Required?
◯ Yes
◯ No
(Methohexital: 10 mg every minute after 2 min, Propofol 20 mg every minute after 2 minutes)

Number of Extra Doses
◯ 1
◯ 2
◯ 3
◯ 4
◯ 5

Cardioversion Procedure

Study ID _____

Date of Cardioversion _____

Timed events during cardioversion
Start Stopwatch when anesthesia announces bolus initiated. Hit lap button after each time event.

T1 - Time To LOC (RSS 5 or 6) _____ (MM:SS)

T2 - Time To First Shock _____ (MM:SS)

T3 - Time To Eyes Open _____ (MM:SS, may be to voice or touch)

T4 - Time To Recovery (Able to answer both "What is your name and what is your age?") _____ (MM:SS)

Vitals Measurements Prior To Induction

Heart Rate _____

SBP _____

DBP _____

MAP _____

Respiratory Rate _____

SpO2 _____

Vitals Measurements Prior to First Shock

Heart Rate

SBP

DBP

MAP

Respiratory Rate

SpO2

Vitals Measurements 1 Minute After Shock

Heart Rate

SBP

DBP

MAP

Respiratory Rate

SpO2

Vitals Measurements 3 Minutes After Shock

Heart Rate

SBP

DBP

MAP

Respiratory Rate

SpO2

Vitals Measurements 5 Minutes After Shock

Heart Rate

SBP

DBP

MAP

Respiratory Rate

SpO2

Vitals Measurements 7 Minutes After Shock

Heart Rate

SBP

DBP

MAP

Respiratory Rate

SpO2

Vitals Measurements 9 Minutes After Shock

Heart Rate

SBP

DBP

MAP

Respiratory Rate

SpO2

Vitals Measurements 10 Minutes After Shock

Heart Rate

SBP

DBP

MAP

Respiratory Rate

SpO2

Vitals Measurements 15 Minutes After Shock

Heart Rate

SBP

DBP

MAP

Respiratory Rate

SpO2

Vitals Measurements 20 Minutes After Shock

Heart Rate

_____

SBP

_____

DBP

_____

MAP

_____

Respiratory Rate

_____

SpO2

_____

Vitals Measurements 30 Minutes After Shock

Heart Rate

_____

SBP

_____

DBP

_____

MAP

_____

Respiratory Rate

_____

SpO2

_____

Cardioversion Summary

Successful Cardioversion?

- ◯ Yes
- ◯ No

Number of Cardioversions

- ◯ One
- ◯ Two
- ◯ Three

Maximum Energy Used

- ◯ 50 J
- ◯ 100 J
- ◯ 125 J
- ◯ 150 J
- ◯ 200 J

Joules Used For Each Attempt (Answer if >1 attempt)

	50 J	100 J	125 J	150 J	200 J
DCCV #1	◯	◯	◯	◯	◯
DCCV #2	◯	◯	◯	◯	◯
DCCV #3	◯	◯	◯	◯	◯

Safety Endpoints

Evidence of Bradycardia
◯ Yes
◯ No
(HR < 60 bpm)

Hypotension
◯ Yes
◯ No
(Decrease in SBP >or= 20%)

Were vasopressor agents required?
◯ Yes
◯ No

Hypoxemia
◯ Yes
◯ No
(SpO2 Nadir < 85%)

Jaw Thrust or Chin Lift Required
◯ Yes
◯ No

Bag Mask Ventilation
◯ Yes
◯ No

Invasive Airway Required
◯ Yes
◯ No

Apnea > 20 seconds
◯ Yes
◯ No

World Society of Intravenous Anesthesia (World SIVA) Adverse Event Severity
◯ Minimal Risk Adverse Event
◯ Minor Risk Adverse Event
◯ Moderate Risk Adverse Event
◯ Sentinel Adverse Event
◯ No adverse events
(Select the most severe option from the attached World SIVA Sheet)

Patient Experience

Recall of Pain at the Injection site

no pain — worst imaginable pain

(Place a mark on the scale above)

Unpleasantness of the Procedure

no distress — worst imaginable distress

(Place a mark on the scale above)

Cardioversion Workflow

Patient Arrives

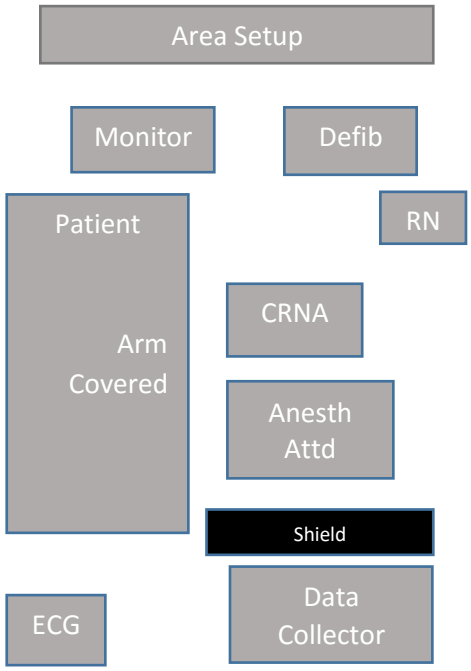
Informed Consent
Inclusion/Exclusion

History and Demographic Collection
- ☐ Demographic Sheet (Use Recdaps)
- ☐ Baseline Data form

Randomization
- ☐ Anessthesia - Randomization form on REDCap

Brevital
0.5 mg/kg (ABW)
- May give extra 10 mg/min after 2 min

Propofol
0.8 mg/kg (ABW)
- May give extra 20 mg/min after 2 min



Needed Items
Stopwatch
Clipboards
Randomization Tool (Redcaps)
Ruler (cm)
Laptop for immediate data input

Needed Forms
Demographics
Baseline Data
Randomization
Cardioversion Procedure
Siva Adverse Event
Patient Experience Form
Consent
Inclusion/Exclusion

Data Collector

- ☐ Baseline Vitals
- ☐ Start Stop watch when bolus announced
- ☐ Record Lap Times
  T1 - Time to LOC, RSS 5 or 6
  T2 - Time to First Shock
  T3 - Type to Eyes Open (touch/voice)
  T4 - Time to recovery, Answer Name and Age
- ☐ Automatic BP set to q 1 min for first 10 min then q 5 min
  Pre DCCV vitals are closest vitals prior to 1st DCCV
- ☐ At 30 min Recovery
  Have pt mark experience scale in REDCap
- ☐ Complete Siva Adverse Event Form
- ☐ Input Data into REDCap

Anesthesiology

- ☐ Randomization form Ready
- ☐ Initiate Randomization
- ☐ Prepare Medication out of sight of pt and data collector
- ☐ Make verbal announcement “bolus starting” to prompt timer start
- ☐ Head tilt/chin lift only if Sat <90%

After Cardioversion
- ☐ Record total Dose
- ☐ Input Data into Redcaps

Addendum A
Patient Contact Script (v6.02.2020)

1. Contact Patients who have a scheduled cardioversion (found on the status board on epic)

2. Good [Morning, afternoon, evening] [Mr/Ms.] [Last name] My name is [Molly Jacobs] I am currently working as a recruiter and data collector for our electrophysiologists.

3. At the Wake Forest Baptist Heart and Vascular Center, our electrophysiologists work collaboratively with cardiologists, cardiothoracic surgeons and other heart and vascular specialists to provide state-of-the-art therapies for patients with simple to complex arrhythmias. In addition, our electrophysiologists are heavily involved with the latest research and clinical trials in cardiac electrophysiology

4. Because you have an upcoming scheduled cardioversion, We would like to offer you the opportunity to consider volunteering to participate in one of our clinical research studies

5. One of our current studies is one randomizing patients who are scheduled for cardioversions (without preceding TEE) to receive either propofol or brevital, two short acting medications currently in use during cardioversions. The Electrophysiologists and Anesthesiologists are comparing the two to see which one leads to a more rapid recovery. This study does not change the end result we are trying to accomplish, which is to try to get you back into normal rhythm. It will only change which sedation we give you.

6. I just wanted to contact you ahead of time so that I may potentially answer any questions you may have.
    a. If no. Ok. We will see you at the time of your cardioversion. Thank you and have a great day [Mr/Ms.] [Last name]

    b. If yes. Try to answer questions based on the attached IRB Informed consent form. We will see you at the time of your cardioversion. Thank you and have a great day [Mr/Ms.] [Last name].

Addendum B

Review retrospective data will be performed to evaluate what was the average Propofol dosing per kg of measured and ideal body weight in patients who meet the criteria of having received an elective cardioversion procedure with Propofol" as outlined in the PI's i2b2 search PR CA-PR EC-Propo@10:13:58 [5-7-2020] [ebeaty].