**h\*\* Objectives**

The primary objective of this study is to evaluate the rate of mineralization and chronic infections in cats with a SUB device where tetra-EDTA was used routinely in SUB device flushing since the time of placement. This will be compared to a historical control group where sterile saline was used for routine SUB flushing, as previously published.

Secondary objectives:

1. To determine if tetra-EDTA is effective in preventing mineralization of the SUB device.
2. To determine if tetra-EDTA is effective in preventing infection in cats with a SUB device indwelling .
3. To determine if tetra-EDTA alters time to device mineralization.
4. To determine if use of tetra-EDTA alters renal parameters at various time points.

**The hypothesis to be tested** is that prophylactic use of tetra-EDTA decreases rate of mineralization and infection in cats with subcutaneous ureteral bypass devices compared to historical controls.

**Tab 1 Pre-Op**

**Descriptive**

* Pre-op range/mean/median for creatinine, renal pelvic size (transverse), age overall and by group
  + Variables: Creatinine, Age , Renal pelvic size ren\_pel\_sz
    - Groups : Overall, EDTA, Saline, Mixed -
      * Range:
      * Mean:
      * Median:
* % each etiology, % hypercalcemia (pct\_hypercalc), pct\_infect for obstruction overall and by group
  + Overall
  + EDTA
  + Saline
  + Mixed
* % infection (PreSx\_UTI) overall and by group
  + Overall
  + EDTA
  + Saline
  + Mixed
* Breakdown of type of Pre\_TypeUTI
  + Overall
  + EDTA
  + Saline
  + Mixed
* % with infection that were on PreAbx72
  + Overall
  + EDTA
  + Saline
  + Mixed
* % with PU\_Sx
  + Overall
  + EDTA
  + Saline
  + Mixed

**Stats**

* Is pre\_iCa (2 = elevated), associated with Stone, Mineralized, TimeMin, Stone\_CompleteOcclude, TimeStoneBlock, Exchange Stone\_Needed, ExchangeStone\_YN, ExchangeStoneComp?

Is pre\_iCa – Independent (1/0)

Dependents:, Mineralized 1/0 coupled with TimeMin (KM, Stone\_CompleteOcclude (0/1), Stone 1/0 TimeStoneBlock(KM), Exchange Stone\_Needed(1/0 – Chisq), ExchangeStone\_YN, ExchangeStoneComp

Response = Outcome = Y = Dependent (what is being influenced or being driven by something)

Drivers = Covariates = Betas = Independent Variables (what is doing the influencing)

Weight is being driven/modelled/influenced by age

Weight (continuous scale of 1-100 or 1000 bell shaped curve) = Age (continuous) : Regression: Is there a linear relationship with age increasing (or decreasing) weight.

Weight (continuous) = Gender (M/F) : ANOVA (Are the mean weights of M vs. F diff

Weight (continuous) = Age (continuous) + Gender (M/F): ANCOVA Taking into consideration

If both variables are Categorical Variables (don’t really have to define DV/IV):

Variable 1: S/M/L

Variable 2: Dead/Alive

Chi-Square Contingency 3 x 2 Table (• Is pre\_iCa ( 2 = elevated), associated with Stone)

|  |  |
| --- | --- |
| 50 | 5 |
| 5 | 40 |

If Response Y/N and you want an odds ratio then Y/N is the dependent variable

Y = mx + b

ANOVA, Regression, ANCOVA

Y = Continuous

Regression: Both continuous

Weight (Y) = X (Age) 0.15 For every one unit of age (years) your weight goes up .15 kg

ANOVA: X = Discrete 1/0, 1,2,3 Small medium large M/F

ANCOVA Y (cont) = (mix) of continuous X and discrete X

Response (Dependent = Y var) Variable 1/0 such as Minearlized (HTF\_mineral) with a continuous independent variable (X or covariate, beta) it is now Logistic Regression (not a Chi-Square)

* Is SUBT\_noEDTA associated with Mineralized, TimeMin, Stone\_CompleteOcclude, TimeStoneBlock, Exchange Stone\_Needed, ExchangeStone\_YN, ExchangeStoneComp?

Picking a model and writing out the combinations:

SUBT\_noEDTA – Independent variable doing the driving and is continuous

HTF\_mineral is 1/0 and being driven

HTF\_mineral (1/0) = SUB\_noEDTA (continuous) : Logistic Regression … will yield an odds ratio with for example… 1.1 …e.g…. for every one unit increase in Sub\_noEDTA.. the odds of being a 1 for HTF\_minearl go up by 10%

Logistic regression, must have 1/0 Response Variable

ANOVA/Regression/ANCOVA all have continuous Y/Response/Outcome/Dependent Variables … they can have a mix of dependent.

Logistic Regression must have 1/0 Response Variable … can have a mix of continuous or categorical independent variables that model/drive the 1/0 response.

Chi-Square must have both categorical variables… but don’t need to have the same number of levels in each group… 2 x 2 … a 2 x 3….because we are looking for contingent associations… see the little chart 2 x 2 above….

Time Models… Kaplan Meier/Cox Models

KM gives the survival curves

Cox Models give Hazard Ratios

If just interested in overall population:

Only need time to end of study… that can be primary event of interest, lost to follow-up, or lost to censoring/some other kind of event causing the patient to leave the study for reasons other than lost to follow-up or primary event… called right censoring… and need event variable 1/0… where 1 is primary event and 0 is lost to follow-up or censored for other reasons.

If interested in differences in groups, then just need well defined group variable coupled with time/event variable.

For time analyses, would need time variable, event (1/0) variable, and group(s)

* Is PreSx\_UTI (1/) associated with UTI\_Post\_Any, SymptomUTI, Chronic UTI, ChronicUTI\_PreandPost? - Chisq
* Is PreSx\_UTI associated with UTI\_Post\_Any, SymptomUTI, Chronic UTI, ChronicUTI\_PreandPost?
* Is Ucath associated with UTI\_Post\_Any? SymptomUTI? Chronic UTI, ChronicUTI\_PreandPost?
* Is PU\_Sx associated with UTI\_Post\_Any? SymptomUTI? Chronic UTI, ChronicUTI\_PreandPost?

All ChiSq

**Tab 2 Procedure**

**Descriptive – Freqs with Chisq**

* % unilateral vs bilateral vs 3-way overall and per group
  + Overall
  + EDTA
  + Saline
  + Mixed
* % IntraComp
  + Overall
  + EDTA
  + Saline
  + Mixed
* % IntraEDTA
  + Overall
  + EDTA
  + Saline
  + Mixed
* % IntraCysto
  + Overall
  + EDTA
  + Saline
  + Mixed
* % PyeloCS (0=we did one and it was negative, 1=positive) vs % PreSx\_UTI
  + Overall
  + EDTA
  + Saline
  + Mixed
* % positive Uculture\_Pyelo\_Result
  + Overall
  + EDTA
  + Saline
  + Mixed

**Stats**

Is stone, stricture, PurulentDebris – Independent (1/0)

Dependents:, Mineralized 1/0 coupled with TimeMin (KM, Stone\_CompleteOcclude (0/1), Stone 1/0 TimeStoneBlock(KM), Exchange Stone\_Needed(1/0 – Chisq), ExchangeStone\_YN, ExchangeStoneComp

* Is etiology (stone, stricture, PurulentDebris) associated with Mineralized, TimeMin, , Stone\_CompleteOcclude, TimeStoneBlock, Exchange Stone\_Needed, ExchangeStone\_YN, ExchangeStoneComp?
* Is etiology (stone, stricture, DSB, PurulentDebris) associated with UTI\_Post\_Any, SymptomUTI, Chronic UTI, ChronicUTI\_PreandPost?
* Is IntraEDTA associated with UTI\_Post\_Any, SymptomUTI, Chronic UTI, ChronicUTI\_PreandPost?

**Tab 3 Post-Op**

**Descriptive**

* Hosp\_Time median, mean, range overall and by group
  + Overall
  + EDTA
  + Saline
  + Mixed
* Creat24hr, BUN24hr median, mean, range overall and by group
  + Overall
  + EDTA
  + Saline
  + Mixed
* DisCreat. DisBUN median, mean, range overall and by group
  + Overall
  + EDTA
  + Saline
  + Mixed

**Tab 4 Follow Up**

**Descriptive**

* SUB\_T median, mean, range overall and by group
* SUBT\_noEDTA median, mean, range for the mixed group only
* PT\_SURV\_T overall and by group
* Cause\_Death overall and by group – Renal and non-renal
* Flush\_Time overall and by group
* % HighCa\_Post overall and by group
* UTI\_number overall and by group
* % low/normal/high HighCa\_Post overall and by group

**Stats**

* Is SUBT\_noEDTA associated with Mineralized, TimeMin, Stone\_CompleteOcclude, TimeStoneBlock, Exchange Stone\_Needed, ExchangeStone\_YN, ExchangeStoneComp?
* Is PT\_SURV\_T associated with group?
* Is DefUreter. DefRenal, LikelyRenal associated with group?
* Is Flush\_Time associated with UTI\_Post\_Any, SymptomUTI, Chronic UTI, ChronicUTI\_PreandPost?
* Is Flush\_Time associated with Mineralized, TimeMin, Stone\_CompleteOcclude, TimeStoneBlock, Exchange Stone\_Needed, ExchangeStone\_YN, ExchangeStoneComp?
* Is Flush\_Time associated with PT\_SURV\_T – coupled with 1/0 did they die and ?
* Is UTI\_Post\_Any, SymptomUTI, Chronic UTI, ChronicUTI\_PreandPost associated with PT\_SURV\_T?
* Is HighCa\_Post (2=high – 1/0) associated with Mineralized, TimeMin, Stone\_CompleteOcclude, TimeStoneBlock, Exchange Stone\_Needed, ExchangeStone\_YN, ExchangeStoneComp(1/0)?
* Is UTI\_number associated with group?

Associated the following binary variables:

HighCa\_Post, …. By : ExchangeStoneComp

**Tab 5 Complications**

**Descriptive**

* Comp\_Overall, Comp\_PeriOp, Comp\_Short, Comp\_Long overall and by group/device
* Leak, Kink, Clot\_periop\_Occlude, Stone\_CompleteOcclude, Mineralized overall and by group
* Median, mean, range TimeMin, TimeStoneBlock overall and by group/device
* Exchange Stone\_Needed, ExchangeStone\_YN, ExchangeStoneComp overall and by group
* Post\_Dysuria, Hematuria\_Gross overall and by group/device
* T1stInfection overall and by group

**Stats**

Descriptive Stats/Mean/Median:

TimeMin, TimeStoneBlock… and other parts of this document into a list

Chi-Square Distilling Down:

Group\*( Comp\_Overall, Comp\_PeriOp, Comp\_Short, Comp\_Long, HTF\_mineral, Stone\_CompleteOcclude) – Something like this

* Is Comp\_Overall, Comp\_PeriOp, Comp\_Short, Comp\_Long associated with group?
* Is HTF\_mineral, Stone\_CompleteOcclude, associated with group?
* Is TimeMin, TimeStoneBlock associated with group?
* Is Exchange Stone\_Needed, ExchangeStone\_YN associated with group?
* Is Post\_Dysuria, Hematuria\_Gross associated with group?
* Is T1stInfection associated with group?
* Is Flush\_Time associated with Post\_Dysuria overall and by group?
* Is long-term creatinine associated with group?

**Tab 6 Imp Trnd**

**Descriptive**

* Median, mean, range Post\_creat\_lastor3mon overall and by group
* % Post\_UTIany, Chronic UTI, ChronicUTI\_PreandPost, SymptomUTI, Post\_Uculture, Post\_Enterococcus, Post\_Ecoli, Post\_Staph overall and by group
* Post\_PelvisAUS overall, by group, by device

**Tab 7 Follow up/ EDTA protocol**

**Descriptive**

* % Hx\_SUBDeminProt by MixedDevices/tEDTAonlydevices combined and individually
* % Hx\_SUBDeminWork by MixedDevices/tEDTAonlydevices combined and individually
* % Hx\_SUBDeminReobstruct by MixedDevices/tEDTAonlydevices combined and individually
* % Hx\_SUBInfectionProt by MixedDevices/tEDTAonlydevices combined and individually

**Stats**

* % Hx\_SUBDeminWork associated with device, group?
* Was Hx\_SUBDeminReobstruct associated with device, group?