Short Term Topical Tetracaine is Highly Efficacious for the Treatment of Pain Caused by Corneal Abrasions: A Double-blind, Randomized Clinical Trial

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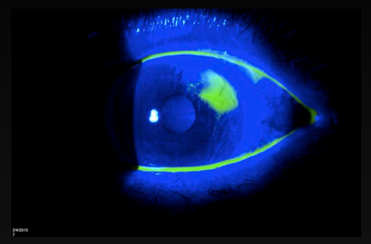
ABSTRACT

Study Objective: The objective of this study was to show that patients with corneal abrasions would experience more pain relief with short term topical tetracaine than placebo.

Methods: The study was a prospective, double-blind, randomized trial of tetracaine versus placebo set in the emergency department (ED). A total of 118 adults who presented with uncomplicated corneal abrasions were included and randomized. The intervention was either topical tetracaine or placebo applied every 30 minutes as needed for 24 hours. The primary outcome was the overall numerical rating scale (NRS) pain score measured at the 24 to 48-hour ED follow-up examination.

Results: 111 patients were included in the final analysis, 56 in the tetracaine group and 55 in the placebo group. At the 24 to 48-hour follow-up, the overall NRS pain score after use of the study drops was significantly lower in the tetracaine group (1) versus placebo group (8) ($\Delta 7$; 95% CI 6,8). Patients in the tetracaine group used less hydrocodone than those in the placebo group. The complication rates between the 2 groups were similar.

Conclusions: Short term topical tetracaine is an efficacious analgesic for acute corneal abrasions, is associated with less hydrocodone use when compared to placebo, and was found to be safe in this sample.



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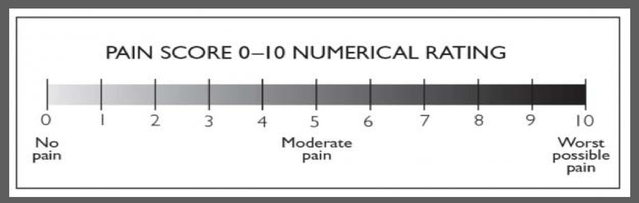
Background

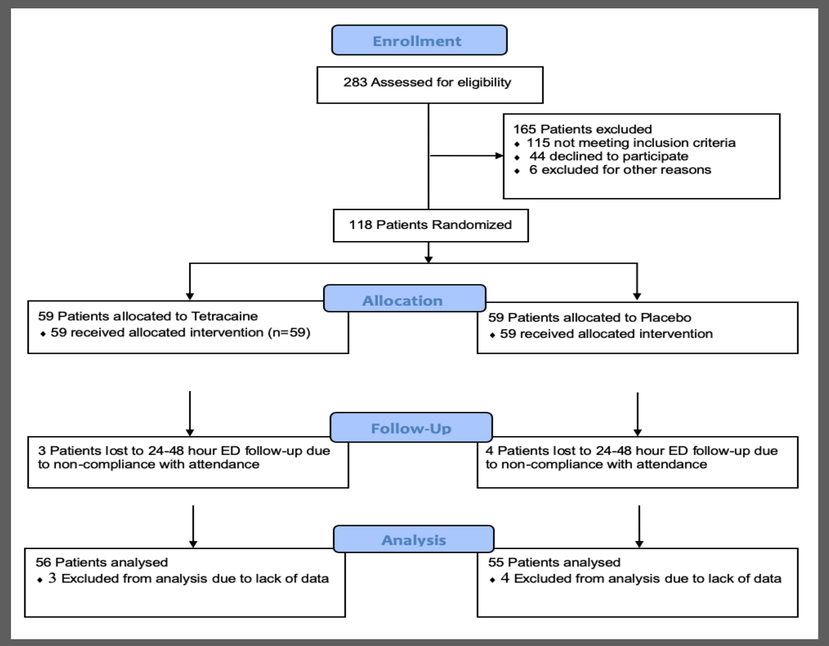
- Corneal abrasions are common Emergency Department complaints.
- Topical anesthetic drops are routinely used as diagnostic therapy but discouraged for outpatient management due reports of rare complications.
- The objective of this study was to compare the effectiveness of topical tetracaine vs placebo in ED patients with corneal abrasions by measuring the Numeric Rating Scale (NRS) pain score at 24 – 48 hour ED follow up.

Methods

- Prospective, randomized, double-blind, placebo-controlled trial.
- Approved by IRB and registered with ClinicalTrials.gov.
- Data collected from Jan 2015 – Sept 2017 in an urban community ED with 86,000 visits/year.
- Patients were randomized to tetracaine or placebo groups using numbered, sealed opaque envelopes.
- Each envelope contained an antibiotic ophthalmic solution (Polytrim) and either tetracaine or placebo labeled as “study drops.”
- Patients also received hydrocodone/APAP 7.5/325 mg #12 for breakthrough pain and asked record amount of hydrocodone taken.
- The primary outcome was the overall numerical rating scale (NRS) pain score measured at the 24 to 48 hour ED follow-up examination.
- The secondary outcome was the number of hydrocodone taken and adverse events.
- Patient were asked to follow up with study ophthalmologist after one week.
- Electronic medical record searched and follow up via telephone.

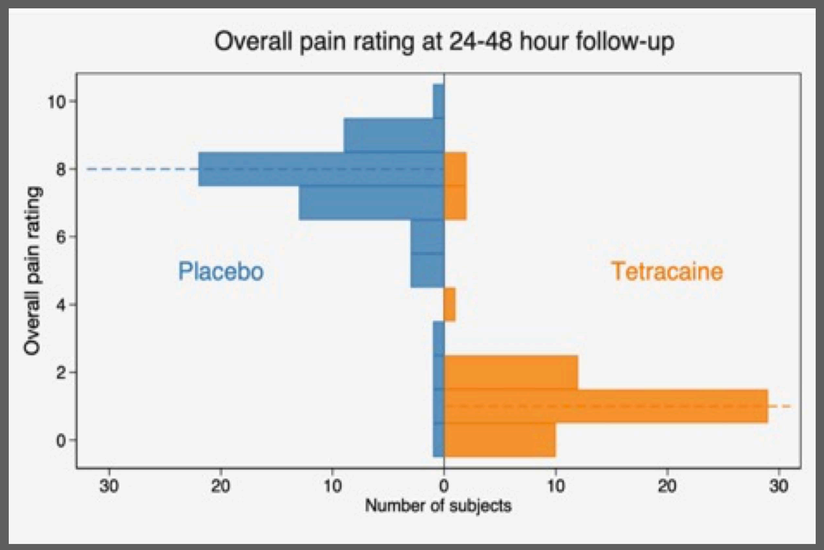


Results



Endpoint	Tetracaine(n=56)	Placebo(n=55)	Difference(95%CI)
Overall NRS at 24-48° follow-up	1(1,2)	8(7,8)	7(6,8)
Secondary endpoint			
Number of hydrocodone tablets recorded	1	7	6(4,9)
Adverse events	3.6%	11%	7.4%(-2.9,18.6)

NRS=Numerical Rating Scale
*Results are expressed median (IQR) unless otherwise indicated.



Conclusions

- Topical tetracaine resulted in significantly lower NRS pain at 24-48 hours as compared to placebo.
- Tetracaine group took less opiates (5.9 tablets) without any increase in complication.
- Tetracaine group recorded use of study drops more.
- This could reduce or eliminate prescription opioid use.
- Our study suggests ED clinicians can safely prescribe patients with uncomplicated corneal abrasions topical anesthesia for 24 hours with close ophthalmology follow up and return precautions.

Limitations

- This study was not powered to establish safety for rare adverse events.
- Burning nature of tetracaine may unintentionally unblinded patients.
- Placebo drops were packaged in 4 ampules vs single bottle of tetracaine.
- Excluded large or complicated cases.
- Single center
- Very few patients in either group attended one week follow up.
- Possibility of missed complications or sought care elsewhere.

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The Impact of Maternal Body Mass Index on Rates of Invasive Monitoring During Labor

Amanda N. Berry, DO PGY-4

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Fetal heart rate monitoring is a tool to aid in the evaluation of fetal oxygenation status during labor. The accuracy of continuous external fetal monitoring decreases as maternal body mass index (BMI) increases. This often necessitates placement of invasive fetal monitoring devices including fetal scalp electrodes and/or intrauterine pressure catheters.

The study was a retrospective chart review. Patients were grouped by maternal BMI at time of admission with 255 patients in the obese group and 178 patients in the non-obese group. Inclusion criteria were ages between 18-45. Exclusion criteria were cesarean delivery without a trial of labor and fetal demise. Data was analyzed using categorical data analyses tests.

Rates of invasive monitoring were significantly greater in the obese group (P=.0001). The use of pitocin for induction of labor or augmentation was also significantly higher in the obesity group (P=.0138). For patients who presented in active labor, the use of both invasive monitoring (P=<.0001) and pitocin (P=<.0001) were significantly decreased.

Our research shows the use of invasive monitoring increases as maternal BMI increases. Patients who present in active labor are less likely to require invasive monitoring or receive pitocin. Invasive monitoring is not without risk and patients should be counseled appropriately on the use of these devices during their labor course. These are risks taken everyday by patients and their providers, often without proper informed consent. Understanding the rates of use by maternal BMI would allow physicians to more appropriately counsel their patients.

The Impact of Maternal Body Mass Index on Rates of Invasive Monitoring During Labor

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Abstract

Fetal heart rate monitoring is a tool to aid in the evaluation of fetal oxygenation status during labor. The accuracy of continuous external fetal monitoring decreases as maternal body mass index (BMI) increases. Increased BMI often necessitates placement of invasive fetal monitoring devices including fetal scalp electrodes and/or intrauterine pressure catheters. Invasive monitoring is not without risk and patients should be counseled appropriately on the use of these devices during their labor course. This study was a retrospective chart review. Patients were grouped by maternal BMI at time of admission with 255 patients in the obese group and 178 patients in the non-obese group. Inclusion criteria were subjects between the age of 18 to 45. Exclusion criteria were cesarean delivery without a trial of labor and fetal demise. Statistics were obtained utilizing categorical data analyses testing. Rates of invasive monitoring were significantly greater in the obese patients during labor (p=.0001). The use of pitocin for induction of labor or augmentation was also significantly higher in the obese group (p=.0138). For patients who presented in active labor, the use of both invasive monitoring (p=<.0001) and pitocin (p=<.0001) were significantly decreased. These results indicate the use of invasive monitoring increases as maternal BMI increases. Patients who present in active labor are less likely to require invasive monitoring or receive pitocin. Understanding the rates of use of invasive fetal monitoring by maternal BMI would allow physicians to more appropriately counsel their patients.

Introduction

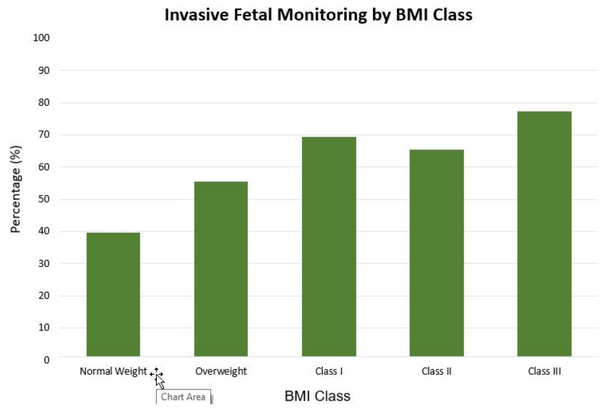
Continuous fetal monitoring during the intrapartum period has become increasingly common over the past several decades. This is because fetal heart rate (FHR) monitoring is used to determine fetal oxygenation status (2). With continuous external fetal monitoring, it becomes increasingly difficult to get an accurate continuous tracing as maternal body mass index (BMI) increases (1). This often necessitates placement of invasive fetal monitoring devices such as fetal scalp electrodes (FSE) and/or intrauterine pressure catheters (IUPC). American College of Obstetricians and Gynecologists (ACOG) guidelines recommend FHR evaluation every 15 minutes during the first stage of labor and every 5 minutes during the second stage, thus the need for accurate determination of FHR and uterine contractions is paramount. Brocato et al. examined how long fetal heart tones (FHTs) went unmonitored in patients from induction to amniotomy and found unmonitored time increased as maternal BMI increased. Ray et al., examined obesity as a whole during intrapartum care and found similar outcomes, that FHTs went unmonitored more often in obese women and lead to increased placements of FSEs and IUPCs. While these studies began to look at the impact of obesity on the accuracy of intrapartum electronic fetal monitoring, there is a lack of data corresponding to rates of FSE and IUPC based on maternal BMI, specifically stratified by BMI class. Without this information the clinician has been unable to accurately educate their patients in clinic appointments about the risks of invasive monitoring leading up to their labor. Risks associated with invasive monitoring differ depending on which device is used. With FSE, there are risks of bruising, laceration, infection, or malplacement into a structure other than the scalp. With IUPC, there are risks of infection or placement into the placenta. With both invasive monitors placed, research shows that rates of cesarean delivery are increased (5). The use of invasive monitoring imparts risks which are taken everyday by patients, often without proper informed consent. With the rates of invasive monitor use potentially dependent on maternal BMI, the clinician would be able to better inform their patients about risks they may be more prone to experience during labor.

Methods

- A retrospective chart review of patients who delivered at Integris Southwest Medical Center between January 1 and December 31, 2018.
- Inclusion criteria: age criteria was between 18 and 45 at time of delivery, and patient must have delivered at INTEGRIS Southwest Medical Center between the dates of January 1 and December 31, 2018.
- Exclusion criteria: any subject younger than 18 years of age or older than 45 years of age, cesarean without attempt of labor, and fetal demise.
- Patients were then grouped based on their BMI classification into either obese or non-obese groups, with the obese group including subcategories of: overweight, class I obesity, class II obesity, or class III obesity. The non-obese group included underweight and normal weight patients.

Results

- After evaluation of inclusion and exclusion criteria, 433 patients were included in this study.
- Of 433 patients, 270 patients required an FSE, IUPC, or both (p=0.0001).
- Of 270 patients requiring FSE and/or IUPC, 178 patients were obese (p=0.0001).
- As BMI class increased, use of invasive fetal monitoring increased.
- Obese patients were more likely to need pitocin induction or augmentation during labor (p=0.0138).
- For patients who did not meet criteria for active labor on admission, use of pitocin (p=<0.001) and invasive fetal monitoring were higher (p=<0.0001) compared to patients admitted in active labor.
- Obese patients were more likely to have larger fetuses (p=0.0109).



Characteristics	Total	BMI status: Obese	BMI status: Non-obese	*p*-Value
Patients – no. (%)	433 (100)	255 (58.9)	178 (41.1)	N/A
Age – yr				0.460[b]
Median	26	26	25	
Range	14 – 43	15 – 43	14 - 43	
Fetus weight (grams)				0.0109[a]
Median	3267	3301	3212	
Range	1650-4383	1650-4242	1875-4383	
Race – no. (%)				0.194[b]
White or Caucasian	187 (43.7)	75 (40.1)	112 (59.9)	
Hispanic or Latino	133 (31.0)	48 (36.1)	85 (63.9)	
Native Hawaiian or Pacific Islander	15 (3.5)	8 (53.3)	7 (46.7)	
Black or African American	61 (14.3)	27 (44.3)	34 (55.7)	
American Indian or Alaskan Native	17 (3.9)	8 (47.1)	9 (52.9)	
Asian	12 (2.8)	9 (75.0)	3 (25.0)	
Other	3 (0.7)	1 (33.3)	2 (66.7)	
Insurance– no. (%)				0.388[b]
Medicaid	283 (69.5)	157 (55.5)	126 (44.5)	
Private	112 (27.5)	73 (65.2)	39 (34.8)	
Veterans Administration	3 (0.7)	2 (66.7)	1 (33.3)	
Champus	1 (0.25)	1 (100)	0 (0)	
Uninsured	8 (2.0)	4 (50.0)	4 (50.0)	
Fetal Scalp Electrode (FSE) – no. (%)				0.317[b]
Utilized	17 (3.9)	12 (70.6)	5 (29.4)	
Not utilized	416 (96.1)	243 (58.4)	173 (41.6)	
Intrauterine Pressure Catheter (IUPC) – no. (%)				0.567[b]
Utilized	49 (11.32)	27 (55.1)	22 (44.9)	
Not utilized	384 (88.7)	228 (59.4)	156 (40.6)	
FSE or IUPC – no. (%)				0.0002[b]
Utilized	204 (47.1)	139 (68.1)	65 (31.9)	
Not utilized	229 (52.9)	116 (50.7)	113 (49.3)	
FSE, IUPC or both – no. (%)				0.0001[b]
Utilized	270 (62.4)	178 (65.9)	92 (34.1)	
Not utilized	163 (37.6)	86 (52.8)	77 (47.2)	
Pitocin– no. (%)				0.0138[b]
Utilized	367 (85.0)	225 (61.3)	142 (38.7)	
Not utilized	65 (15.0)	29 (44.6)	36 (55.4)	
Delivery type – no. (%)				0.077[b]
Spontaneous vaginal delivery	339 (78.3)	190 (56.0)	149 (44.0)	
Primary low transverse cesarean section	69 (15.9)	46 (66.7)	23 (33.3)	
Vacuum assisted vaginal delivery	24 (5.5)	18 (75.0)	6 (25.0)	
Repeat low transverse cesarean section	1 (0.23)	1 (0.23)	0 (0)	

[a]Wilcoxon-Mann-Whitney test
[b]Fisher's exact test

	Total	Active labor	Not active labor	
Pitocin– no. (%)	402 (100)	100 (24.9)	302 (75.1)	<0.0001[c]
Utilized	345 (85.8)	62 (18.0)	283 (82.0)	
Not utilized	57 (14.2)	38 (66.7)	19 (33.3)	
Delivery device – no. (%)	403 (100)	100 (24.8)	303 (75.2)	<0.0001[c]
FSE, IUPC, or both	256 (63.5)	35 (13.7)	221 (86.3)	
Neither	147 (36.5)	65 (44.2)	82 (55.8)	

[c]Chi-Square

Conclusions

The primary outcome of this study showed that the use of invasive fetal monitoring is increased in patients who are obese compared to non-obese patients. This increases longitudinally within the obesity classes with the highest risk for invasive fetal monitoring in the class III obesity group. The secondary outcomes of statistical significance were as follows. First, that rates of pitocin administration were increased in those within the obesity group. Second, if patients were admitted in active labor the use of both pitocin and invasive fetal monitoring was decreased. Thus, these patients were less likely to undergo the risks associated with invasive fetal monitoring. Physicians should use this information during prenatal visits to counsel their obese patients about the possible need for both invasive fetal monitoring as well as pitocin administration during their labor course. Strengths of this study include the moderate case numbers with several statistically significant values based on maternal BMI class. A weakness of this study is that patients are selected from only one inter-community hospital. Future research is needed to further analyze the cost effectiveness of both devices. We hope that implications of this study will further encourage physicians to have in-depth counseling during the antenatal period regarding the risks versus benefits of invasive fetal monitoring during labor.

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Utilizing the Electronic Health Record to Increase Advance Care Planning and Improve Access to Advance Directives

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A recent quality improvement project to increase the number of ACP discussions we were having in our rural, outpatient clinic shed light on the fact that even once collected, advance directives (ADs) were difficult to access in our electronic health record (EHR). The current quality improvement project was undertaken with the goal of improving access to ADs by allowing medical staff to quickly determine if a patient has an advance directive on file and hasten retrieval if the document exists. We conceptualized and implemented an access icon that secondarily serves as an illuminating prompt for physicians to assist in ACP and composition of ADs when documentation is not scanned into the patient's chart. Medical staff were surveyed, pre- and post-implementation and demonstration of the icon, on their confidence in their ability to quickly determine if an AD is present in the EHR and ability to retrieve the document if present. Baseline data revealed that only 6.8% of patients empaneled to our resident physicians have existing, scanned documents in their electronic charts, and our medical staff were not confident that they could easily locate or retrieve scanned ADs in a timely manner. The post-implementation survey showed a statistically significant difference in the number of medical staff members confident in their ability to easily locate and retrieve ADs in a timely manner. Since its implementation, the access icon has improved ease-of-use for our medical staff, simplified access to ADs, and should continue to increase ACP within our clinical setting.

Utilizing the Electronic Health Record to Increase Advance Care Planning and Improve Access to Advance Directives

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INTRODUCTION

Just as there are barriers to advance care planning (ACP) and composition of the advance directive (AD), there are obstacles to overcome in implementation of completed ADs. One previously reported health-system related factor is access to the AD. A recent quality improvement project to increase the number of ACP discussions we were having in our rural, outpatient clinic shed light on the fact that even once collected, ADs were difficult to access in our electronic health record. We found it to be cumbersome to determine if a patient had a scanned directive document on file and to extract the AD for use in end-of-life scenarios that require rapid retrieval.

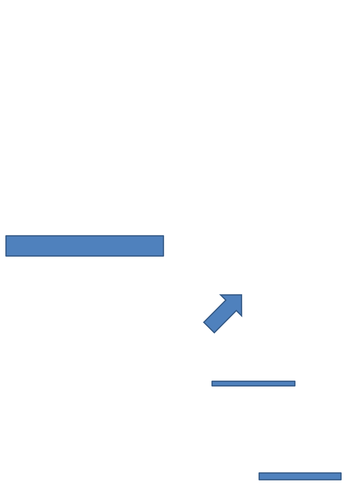
OBJECTIVES

The current quality improvement project was undertaken with the goal of improving ease-of-use of our electronic health record in order to quickly determine if a patient has an advance directive on file and hasten retrieval if the document exists. In addition, we hope that the access icon created for this purpose will serve as a reminder for physicians to increase documentation of patients' wishes by encouraging advance care planning.

METHODS

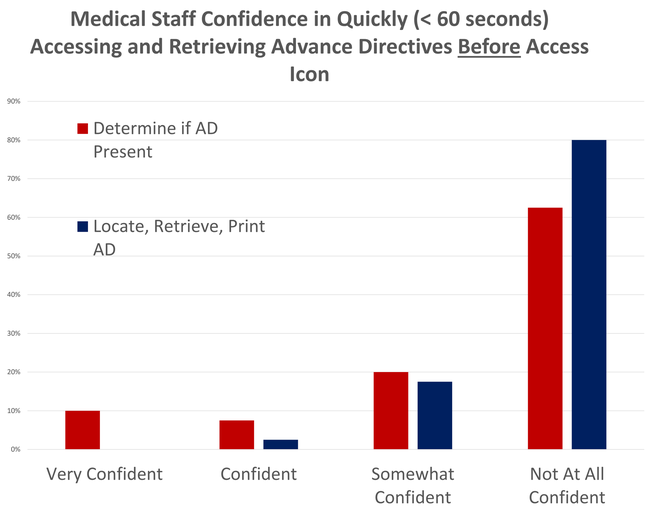
- This ongoing, multi-dimensional effort first included a policy change to ensure that ADs are honored in all clinical settings within our health system.
- Next followed conceptualizing and programming the access icon in our electronic health record that secondarily serves as a prompt to physicians to assist in ACP and composition of ADs when such documentation is not scanned into the patient's chart.
- Before implementation of the icon, we surveyed medical staff on their confidence in ability to determine the presence of an AD or locate, retrieve, and print the AD.
- We repeated this survey after implementation of the access icon and demonstration of its use.
- We also collected baseline data on the percentage of patients empaneled to our residency clinic with an AD currently scanned in the electronic health record.

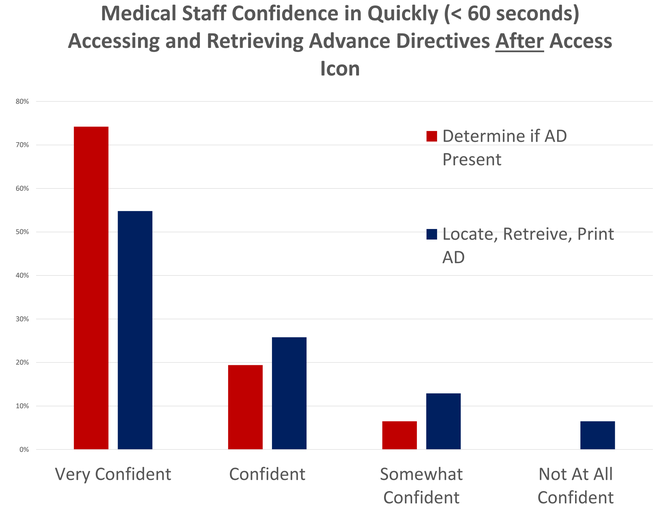
Electronic Health Record Access Icon



- Prior to implementation of the access icon, users had to search through a list of scanned documents to determine if an AD was present
- Now, the icon illuminates red if an AD is scanned
- When clicked, the icon displays the date (within 1-2 days) the document was scanned, allowing the user to quickly search the scanned document list
- Lack of illumination (grey color) of the icon may also serve as a reminder to complete advance care planning

RESULTS





Future Direction: We will query data every 3 months and use Plan-Do-Study-Act cycles of quality improvement to determine the efficacy of the reminder function of the icon. Our aim will be continuing to increase advance care planning performed, specifically in the residency clinic.

CONCLUSIONS

- For confidence in ability to quickly determine the presence of an AD, the mean confidence score (on a 1-4 scale of not confident to very confident) improved from 1.65 to 3.68 ($p<0.0001$)
- For confidence in ability to quickly locate, retrieve, and print an AD, the mean confidence score improved from 1.23 to 3.29 ($p<0.0001$)
- The access icon significantly improved medical staff confidence in ability to quickly access and retrieve ADs.

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