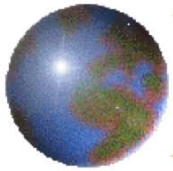

Welcome!

- American hospitals crawling towards Electronic Medical Records (EMR) and Computerized Physician Order Entry (CPOE)
  - Still <10% of US Hospitals
- Must reconcile different information systems to exchange data accurately and efficiently
- Benefits of complete patient data records can be huge
  - Speakers to address benefits at various levels of healthcare administration

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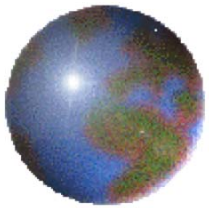

UCSD Medical Center: Database Driven Decisions

Robert Schoenhaus, Pharm.D.
Pharmacoeconomics Specialist
MUE Coordinator

Objectives

- Describe limitations of data decision support at a single academic medical center
- Demonstrate value of coordinated data to drive appropriate patient care through informed decision making
- Review case examples of UCSD medication use evaluations that incorporated patient outcomes taken from several databases

UCSD Pharmacy Data Collection

Siemens Pharmacy
- Pt Demographics
- Drug/dose
- Pharmacy notes

UHC Clinical Resource Management
- Benchmarking outcomes
- Pt diagnosis and Procedure codes

The "Whole" UCSD Pharmacy picture

TSI (mainframe)
- Financial cost/charge by cost center
- Itemized down to the unit
- Coding data

Medical Chart
- Everything else…
- Clinical rationale
- "intangibles"

Data Capture

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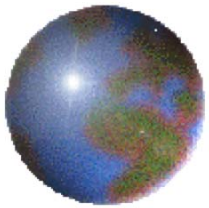


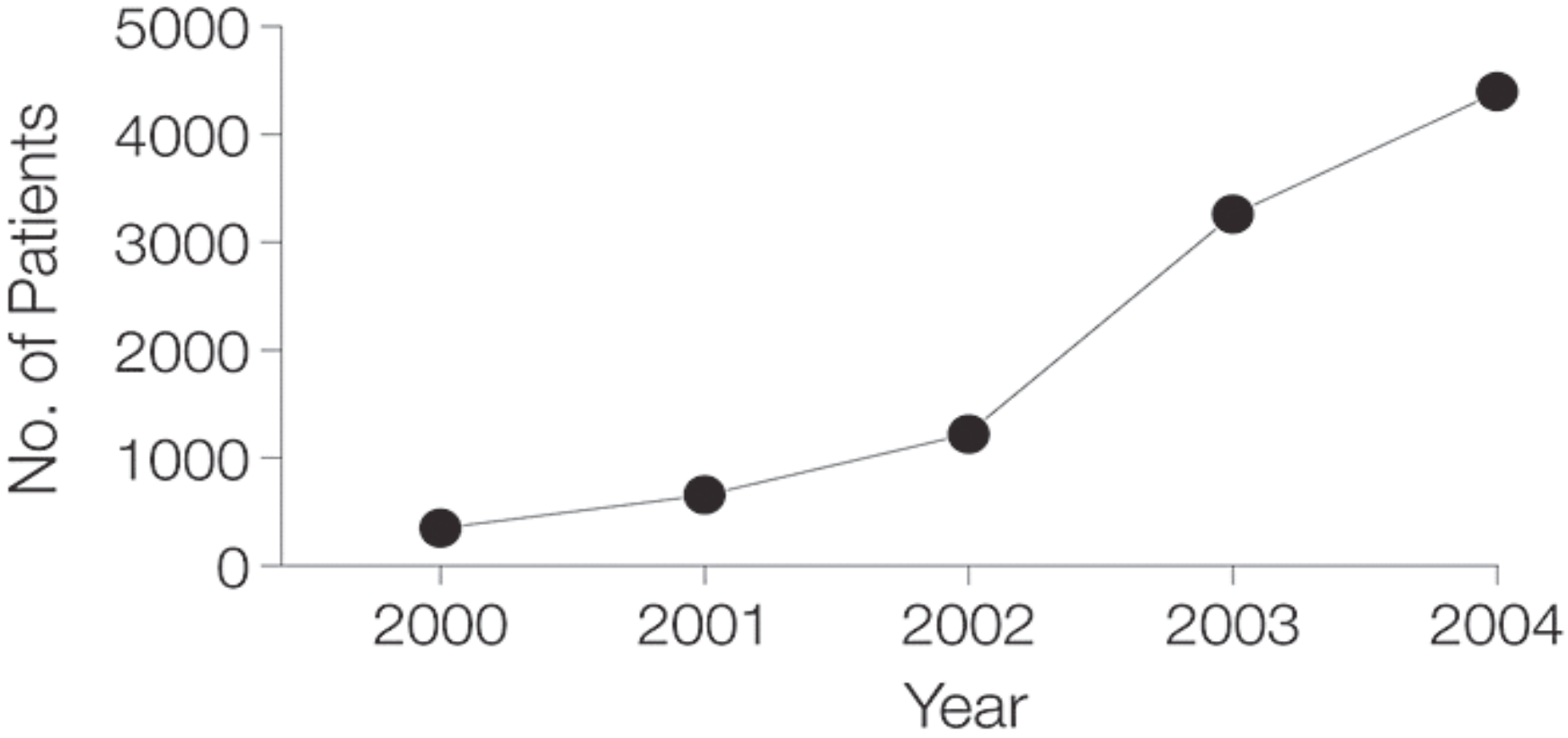
A Single Center Experience with Recombinant Factor VIIa in Orthotopic Liver Transplantation

Robert Schoenhaus Pharm.D, Linda Awdishu BScPhm, MAS; Sam Martinez Pharm.D, Marquis Hart MD, Thomas Lane MD; UC San Diego Medical Center

Introduction

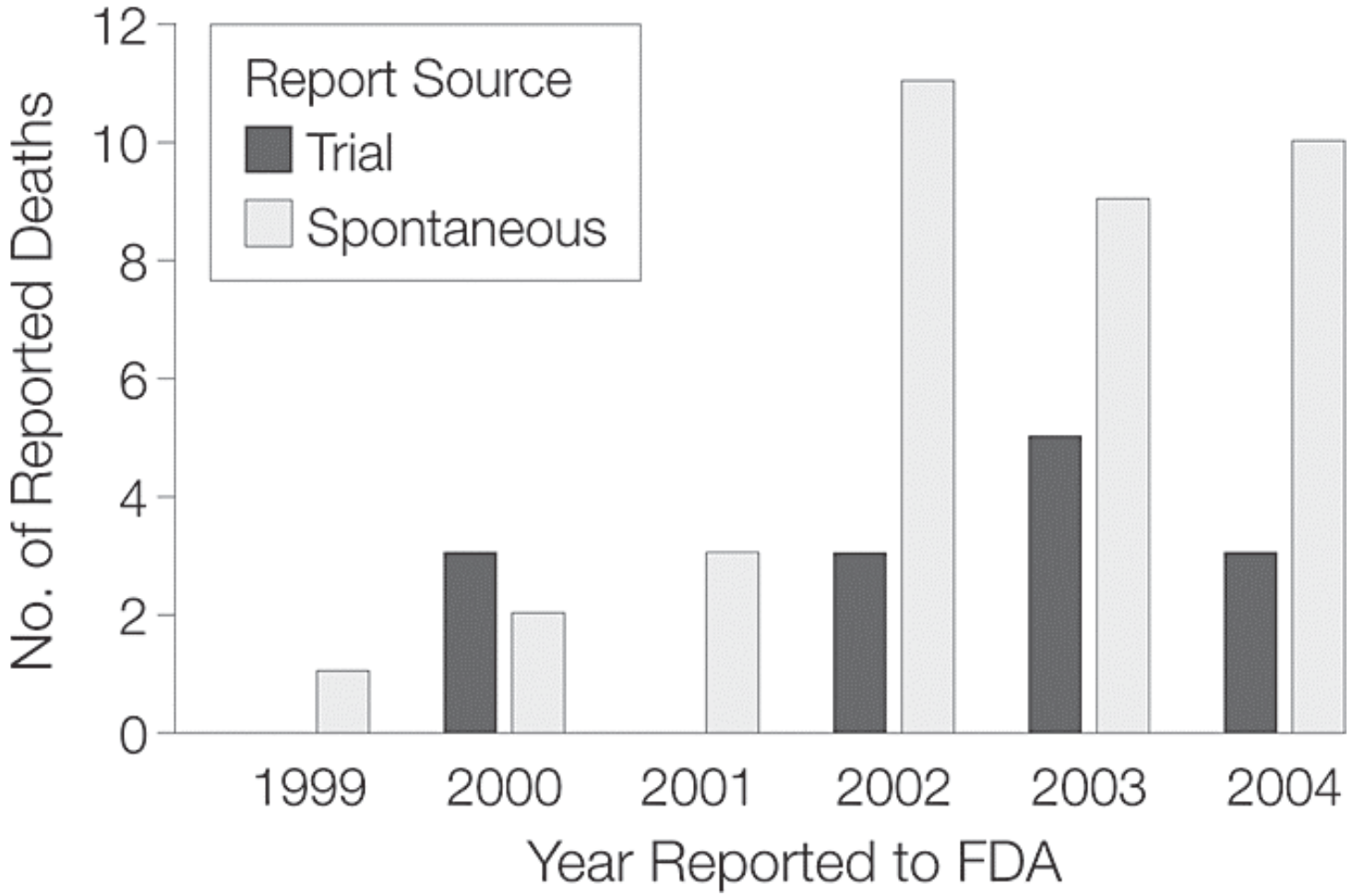
- Options for treatment of blood loss during liver transplantation:
  - Packed red blood cells
  - Platelets
  - Fresh frozen plasma
  - Cryoprecipitate
  - Vitamin K
  - Factor VIIa ?

Estimated Number of Patients Treated With Recombinant Human Coagulation Factor VIIa by Year



O'Connell, K. A. et al. JAMA 2006;295:293-298.

Number of Reported Deaths Among Patients Administered Human Coagulation Factor VIIa With a Thromboembolic Event by Year



O'Connell, K. A. et al. JAMA 2006;295:293-298.

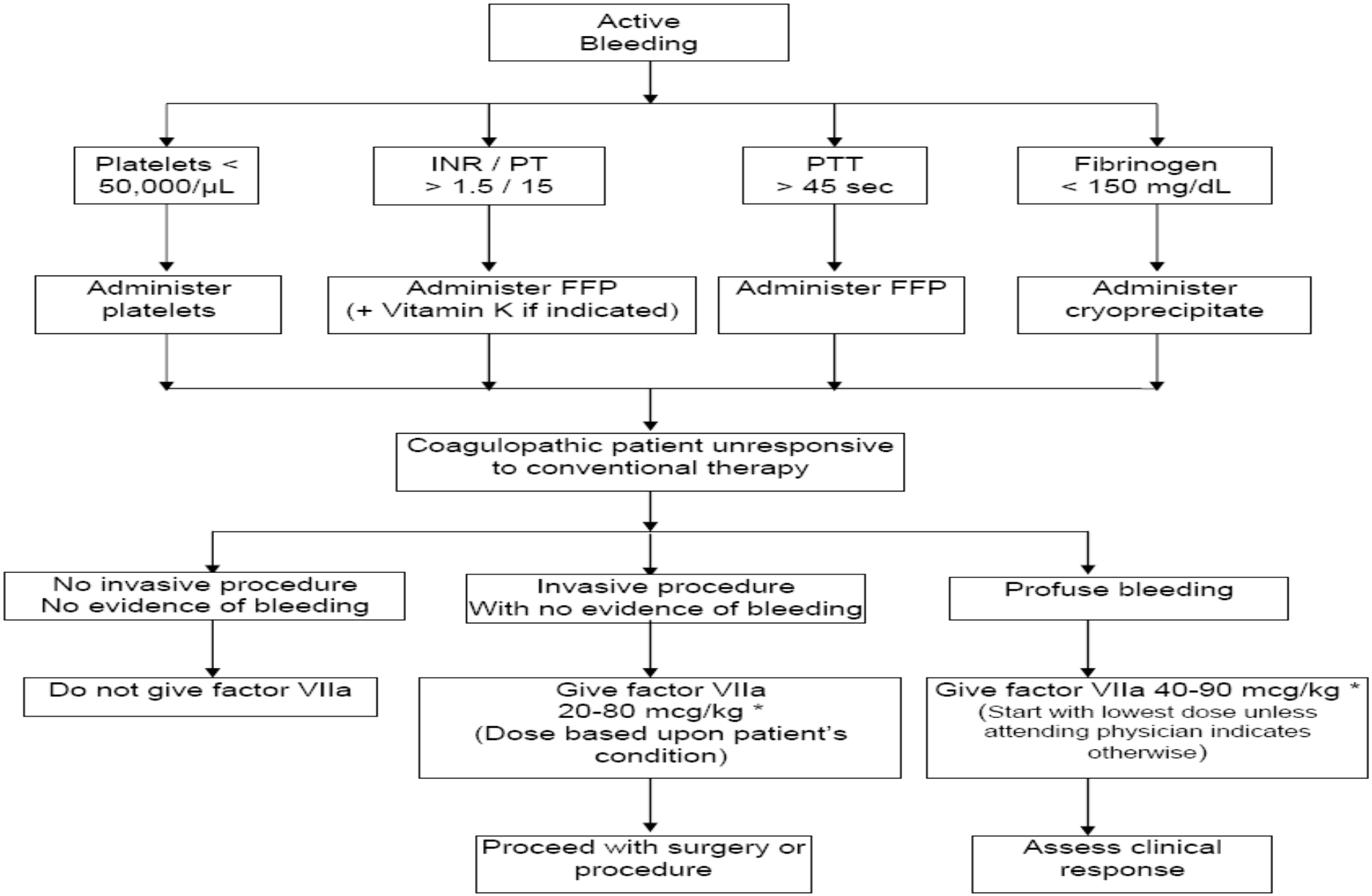
Comparison of Published Literature

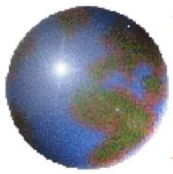
Parameter	Lodge et al (N = 82) (Control versus treatment)	De Gasperi et al (N = 12) (Control versus treatment)	Planinsic et al (N = 183) (Control versus treatment)
Estimated Blood Loss (mL)	NR	**3,500 vs. 1,800**	NR
Packed Red Cells (units)	**8.2 vs. 7**	7 vs. 9	**11.1 vs. 13**
Fresh Frozen Plasma (units)	11 vs. 9.4	21 vs 17	11 vs 15.5
Platelets	141 ml vs 81.8 ml	2.6 units vs 1.5 units	4 units vs 9 units

No significant differences

UCSD Medical Center

RECOMBINANT FACTOR VIIa ALGORITHM





Study Objectives

- Investigate use of factor VIIa in orthotopic liver transplant patients
- Determine if factor VIIa reduces blood product requirements and operating room time in orthotopic liver transplant (OLT) patients
- Alter UCSDMC guidelines if needed

Study Design

- Retrospective, single center study
- **Inclusion:**
  - Patients receiving an OLT
- **Exclusion:**
  - Patients less than 18 years of age
  - Retransplantation
  - Multi-organ transplants
  - ECMO patients
- Data collected from patients admitted between January 2003-November 2006
  - Analyzed 119 patients

Model for End Stage Liver Disease (MELD)

- Numerical scale from **6 (less ill)** to **40 (more ill)** that determines the severity of illness for a patient with end stage liver disease based on the following variables
  - INR
  - Bilirubin
  - Creatinine

Methods

- Data collected
  - Estimated blood loss (EBL) during transplantation
  - Blood product administered (in the OR and at 24 hrs)
  - Operating room time (warm ischemia time, cold ischemia time)
  - CBC, chemistries, coagulation studies from the 24h preceding OLT through 24h after OLT

Methods

- Cost Analysis:
  - Total cost of care is assessed based on:
    - Accommodations cost
    - Pharmacy cost
    - Laboratory cost
    - Blood cost
    - Radiology cost
    - Operating room cost (billed by minute)
    - Transplant (organ) cost

Data Capture (FVIIa)

Statistics

- Primary Outcome
  - Log transformation for blood products (non-normal distribution)
    - T-test for two independent samples
- Secondary Outcomes
  - Length of stay
    - Mann Whitney Test for two samples
  - Total Costs
    - Mann Whitney Test for two samples

Baseline Characteristics

	Control Group (N=51)	Factor VIIa Group (N=68)
Male	68%	63%
Median Age (years)	51 (25-67)	52 (25-68)
Median Weight (kg)	83 (43-122)	80 (49-145)
Median pre-op MELD	16.9 (6-35)	15.9 (6-40)
Median pre-op INR	1.5 (0.9-2.6)	1.4 (0.8-6.5)

No significant differences

Primary Outcomes

Variable	Control (units)	Factor 7a (units)	P Value
Mean PRBC	13.4 ± 14.3	13.8 ± 19.5	
Mean logPRBC	2.2	2.1	0.66
Mean FFP	15.6 ± 20.5	11.3 ± 13.4	
Mean Log FFP	2.4	2.2	0.36
Mean PLT	6.6 ± 10	4 ± 3.5	
Mean LogPLT	1.6	1.3	0.7

No significant differences

Secondary Outcomes

Variable	Control	Factor 7a	P value
Median LOS	10 days (1 - 55)	12 days (0 - 298)	0.46
Median Blood Costs	$5,954 ($517- 42,254)	$6,154 ($563 - 55,742)	0.79
Median Surgical Costs	$6,821 ($1088 - 19,756)	$6,667 ($541 - 27,509)	0.85
Median Total Costs	$57,279 ($33,096 - 166,673)	$55,811 ($32,567 - 479,735)	0.89

No significant differences

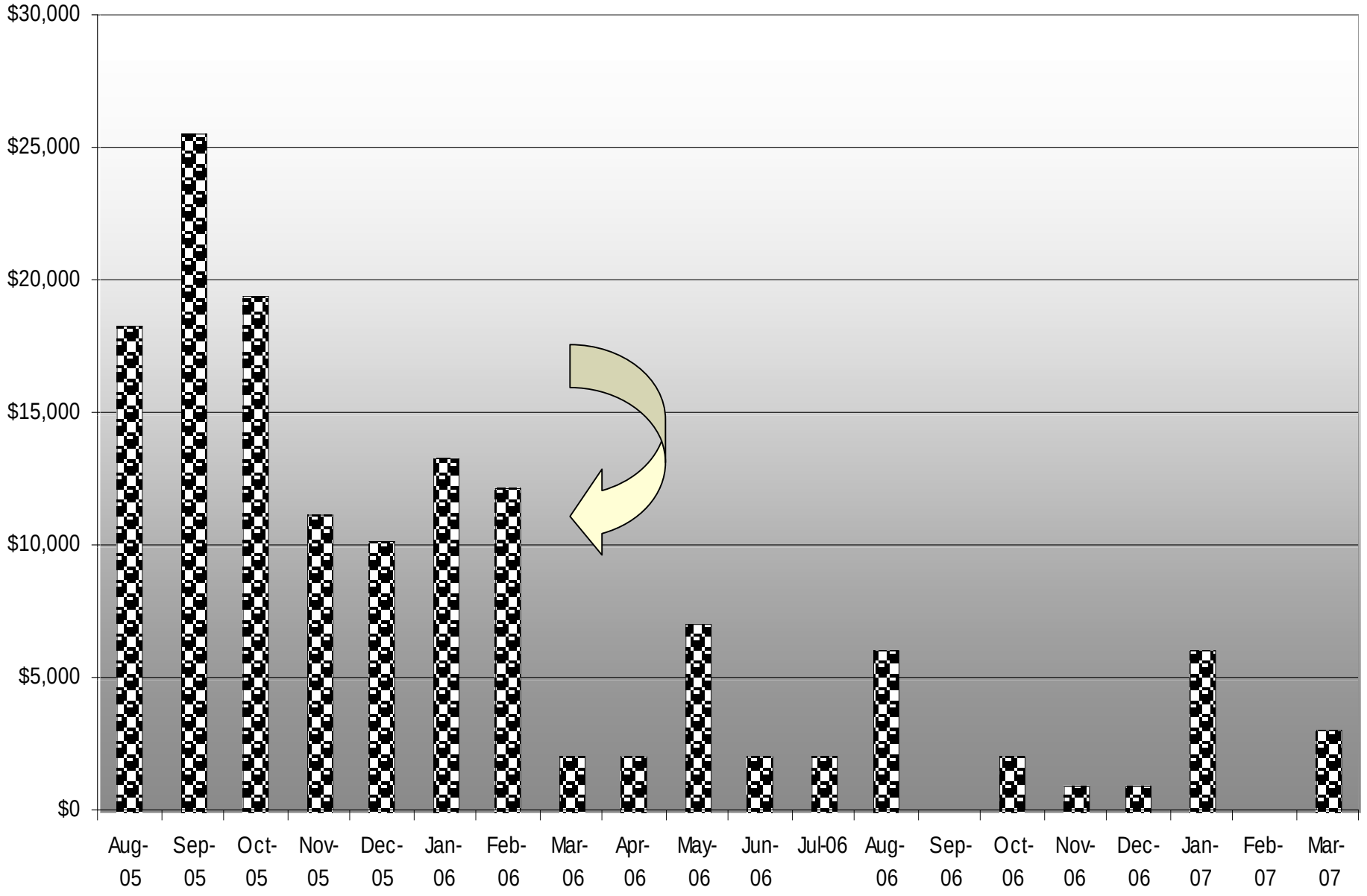
Results

- Thrombosis events
  - 2 thrombosis events in factor 7a group
  - 1 thrombosis event in control group
- Factor 7a Dose
  - Median dose 1.7 mg (0.6 - 8.4)

Conclusions

- The use of factor VIIa appears to not have a significant effect on the amount of red blood cells used
- The results are consistent with the currently available literature that the use of factor VIIa does not provide a benefit in reduction of blood product usage
- No difference between blood product cost, surgical costs or total cost of care

Factor VIIa Utilization; UCSD Liver Transplant Service



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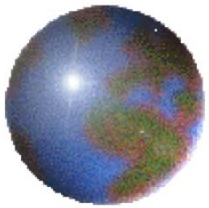


The Use and Outcomes of Antifibrinolytic Therapy in Cardiothoracic Surgery Patients at 20 US Academic Medical Centers

Robert Schoenhaus PharmD, Jim Lane PharmD; UC San Diego Medical Center

Karl Matuszewski PharmD, Mary Ellen Bonk PharmD, Michael J. Oinonen PharmD, MPH; University HealthSystem Consortium

Background

- Impaired hemostasis and blood loss is of concern in patients undergoing cardiac surgery
- Antifibrinolytics (Aprotinin, Aminocaproic Acid and Tranexamic Acid)
  - Safety questioned
    - Mangano DT, et al. The Risk Associated with Aprotinin in Cardiac Surgery. *NEJM*. 2006;354(4): 353-365. (increased risk of adverse renal, cardiovascular, and cerebrovascular events)
    - September 27, 2006, Bayer Pharmaceuticals told FDA that use of Trasylol may increase the chance for death, serious kidney damage, congestive heart failure and strokes
- Our objective was to examine these findings using a larger, more recent dataset from a database of academic medical centers across the US

Methods

Data Source

- University HealthSystem Consortium's Clinical Resource Manager Database
  - Quarterly data feeds of administrative data from 50+ academic medical centers

Inclusion Criteria

- Patients discharged between October 2002 and September 2005 within UHC's Cardiothoracic Surgery (CTS) product line [Diagnostic Related Groups of cardiac surgery in nature (i.e., CABG, Valve, etc)]

Exclusion

- Patients receiving multiple AF agents
- All tranexamic acid pts (only 17 pts from 4 total hospitals)

Three Groups

- Aminocaproic Acid (AA) n = 9,751 pts
- Aprotinin (AP) n = 6,855
- No AF agent/control n = 46,123 pts

Methods, Cont'

Elements Collected

- Demographics (i.e. age, gender, race, etc)
- Comorbidities (Flagged by Comorbidity Software Version 3.1, Agency for HealthCare Research and Quality)
  - Hypertension
  - Diabetes (250.00-250.33, 648.00-648.04, not in DRG 294, 295)
  - Diabetes w/CC (250-40-250.93, 775.1, not in DRG 294, 295)
  - Peripheral Vascular Disease
  - Ace inhibitor utilization
- Outcomes
  - In-hospital mortality
  - Hemodialysis (procedure code 39.95)
  - Acute renal failure (diagnosis code 584.x)
  - Blood Transfusions (procedure code 99.0X)
  - Post-op Stroke (UHC complication profiler, post-op CVA secondary diagnosis without a nervous system DRG assignment)

Initial Screen for Differences

- Logistic regression with control for influential variables:

Demographics	Comorbidities
Age	ACEI use
Sex	Diabetes
Race	Diabetes_cc
	HTN
	PVD
	Renal failure

Patient Count

- **All CTS patients**
  - Aprotinin (N = 6,855)
  - Aminocaproic acid (N = 9,751)
  - Control (N = 46,123)
- **CABG only**
  - Aprotinin (N = 3,066)
  - Aminocap (N = 7,064)
  - Control (N = 6,879)

Results

- Blood Transfusions
- Acute Renal Failure
- Hemodialysis
- Post-OP Stroke
- Mortality

Efficacy

Blood Transfusions	P value	Odds Ratio	95% Confidence Limits	
All CTS Pts Aprotinin vs. Aminocap	***P = 0.966***	0.999	0.934	1.068
CABG only Aprotinin vs. Aminocap	P = 0.0288	0.906	0.830	0.990

Acute Renal Failure Secondary ICD-9 Diagnosis = 584.X	P value	Odds Ratio	95% Confidence Limits	
All CTS Pts Aminocap vs. Control	P < 0.2055	1.069	0.964	1.187
All CTS Pts Aprotinin vs. Control	P < 0.0001	2.291	2.088	2.515
All CTS Pts Aprotinin vs. Aminocap	P < 0.0001	2.056	1.827	2.313
CABG only Aminocap vs. Control	P < 0.0029	0.809	0.703	0.930
CABG only Aprotinin vs. Control	P < 0.0001	1.656	1.428	1.922
CABG only Aprotinin vs. Aminocap	P < 0.0001	2.038	1.746	2.378

Hemodialysis Secondary ICD-9 procedure = 39.95	P value	Odds Ratio	95% Confidence Limits	
All CTS Pts Aminocap vs. Control	*P < 0.1142*	1.119	0.973	1.287
All CTS Pts Aprotinin vs. Control	P < 0.0001	3.034	2.691	3.420
All CTS Pts Aprotinin vs. Aminocap	P < 0.0001	2.709	2.296	3.196
CABG only Aminocap vs. Control	P < 0.0008	0.693	0.560	0.858
CABG only Aprotinin vs. Control	P < 0.0001	2.378	1.935	2.921
CABG only Aprotinin vs. Aminocap	P < 0.0001	3.406	2.734	4.244

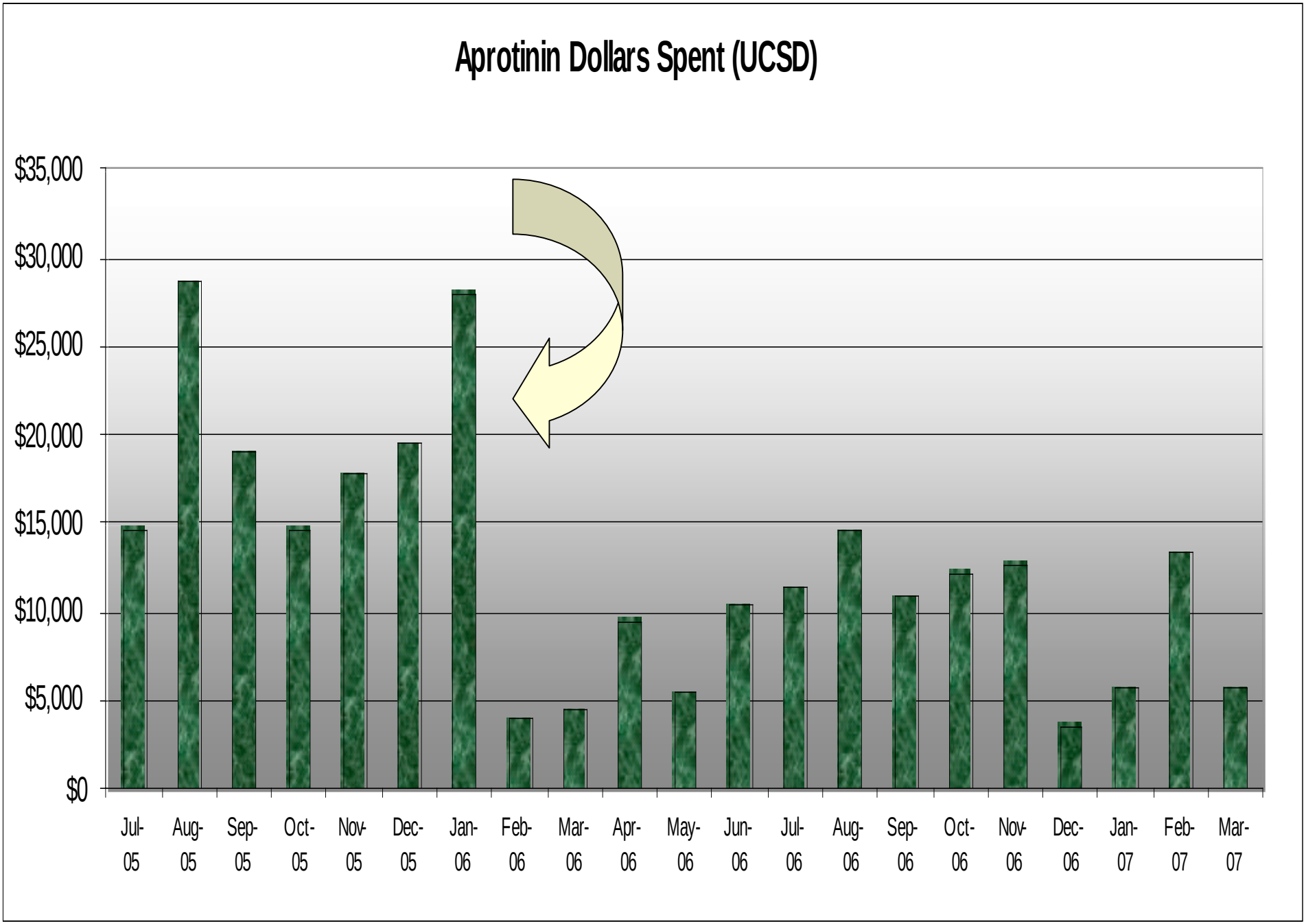
Mortality (In Hospital)	P value	Odds Ratio	95% Confidence Limits	
All CTS Pts Aminocap vs. Control	P < 0.0041	0.801	0.689	0.932
All CTS Pts Aprotinin vs. Control	P < 0.0003	1.271	1.116	1.448
All CTS Pts Aprotinin vs. Aminocap	P < 0.0001	1.775	1.490	2.115
CABG only Aminocap vs. Control	P < 0.0206	0.766	0.612	0.960
CABG only Aprotinin vs. Control	P < 0.0005	1.496	1.192	1.878
CABG only Aprotinin vs. Aminocap	P < 0.0001	1.969	1.547	2.507

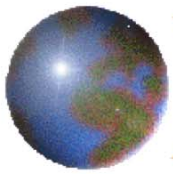
Post-Op Stroke	P value	Odds Ratio	95% Confidence Limits	
All CTS Pts Aminocaproic Acid vs. control	P < 0.0001	2.866	2.336	3.518
All CTS Pts Aprotinin vs. control	P < 0.0001	4.123	3.345	5.083
All CTS Pts Aprotinin vs. Aminocap	P = 0.0006	1.506	1.191	1.905
CABG only Aminocaproic vs. control	P = 0.0012	1.722	1.240	2.392
CABG only Aprotinin vs. control	P < 0.0001	2.177	1.502	3.155
CABG only Aprotinin vs. AA	P = 0.1331	1.290	0.925	1.798

Conclusions

- Aprotinin appeared to have superiority for reducing blood transfusions in CABG population, but was strongly correlated with negative outcomes: ARF, hemodialysis, and mortality
  - Similar to Bayer findings (exc. CHF)

Aprotinin Dollars Spent (UCSD)





Questions?