

Pan computed tomography versus selective computed tomography in stable, young adults after blunt trauma with moderate mechanism: A cost-utility analysis

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BACKGROUND:	Pan computed tomography (PCT) of the head, cervical spine, chest, abdomen, and pelvis is a valuable approach for rapid evaluation of severely injured blunt trauma patients. A PCT strategy has also been applied for the evaluation of patients with lower injury severity; however, the cost-utility of this approach is undetermined. The advantage of rapidly identifying all injuries via PCT must be weighed against the risk of radiation-induced cancer (RIC). Our objective was to compare the cost-utility of PCT with selective computed tomography (SCT) in the management of blunt trauma patients with low injury severity.
METHODS:	A Markov model-based, cost-utility analysis of a hypothetical cohort of hemodynamically stable, 30-year-old males evaluated in a trauma center after motor vehicle crash was used. CT scans are performed based on the mechanism of injury. The analysis compared PCT with SCT over a 1-year time frame with an analytic horizon over the lifespan of the patients. The possible outcomes, utilities of health states, and health care costs including RIC were derived from the published medical literature and public data. Costs were measured in US 2010 dollars, and incremental effectiveness was measured in quality-adjusted life-years (QALYs) with 3% annual discounted rates. Multiway sensitivity analyses were performed on all variables.
RESULTS:	The total cost for blunt trauma patients undergoing PCT was \$15,682 versus \$17,673 for SCT. There was no difference in QALYs between the two populations (26.42 vs. 26.40). However, there was a cost savings of \$75 per QALY for patients receiving PCT versus SCT (\$594 per QALY vs. \$669 per QALY).
CONCLUSION:	PCT enables surgeons to identify and rule out injuries promptly, thereby reducing the need for inpatient observation. The risk of RIC is low following a single PCT. This cost-utility analysis finds PCT based on mechanism to be a cost-effective use of resources. (<i>J Trauma Acute Care Surg.</i> 2014;77: 527–533. Copyright © 2014 by Lippincott Williams & Wilkins)
LEVEL OF EVIDENCE:	Economic and value-based evaluations, level II.
KEY WORDS:	Pan-CT; selective CT; blunt trauma; cost-utility analysis.

Advances in computed tomography (CT) scanning have dramatically changed the evaluation and treatment of trauma patients in recent decades. Pan CT (PCT) clearly plays a crucial role in the management of severely injured blunt trauma patients and can reduce mortality, morbidity, and the time required to identify and treat potentially life-threatening injuries.^{1–5}

The success of PCT in the evaluation of the severely injured has led to its widespread use in less severely injured blunt trauma patients, but the role of PCT in this setting is not clear. PCT can be beneficial in this population, enabling early identification of injuries while obviating the need for serial abdominal examinations and observation.⁶ In addition, PCT has been shown to decrease hospital resource use after ground-level falls in the elderly.⁷ However, these benefits do not come without a price. PCT has an associated risk of radiation-induced cancer (RIC), which may have significant quality-of-life implications for patients and the society.^{8,9} In

addition, PCT can lead to unnecessary workup of clinically irrelevant findings and contrast-induced nephropathy.

Selective CT (SCT) has been shown to be equally effective as PCT when paired with evidence-based guidelines.¹⁰ However, when choosing a CT strategy, there are many things to consider: cost of CT scans, patient observation, treatment of patients with missed injuries, RIC, as well as the patient's quality of life must all be carefully balanced.

Our goal was to analyze the PCT strategy versus the SCT strategy in stable blunt trauma patients with a moderate mechanism of injury by performing a Markov model cost-utility analysis. Specifically, we wanted to identify which approach was cost-effective while taking into account the effects on quality of life. Our hypothesis was that a PCT strategy is more cost-effective than an SCT strategy.

PATIENTS AND METHODS

Study Design

This is a cost-utility analysis, from a health care perspective, evaluating a narrow subset of patients to minimize confounding variables. Our hypothetical cohort included hemodynamically stable 30-year-old males after a motor vehicle crash with moderate mechanism. They had a low mean Injury Severity Score (ISS) of 5, had Glasgow Coma Scale (GCS)

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score of 14 to 15, had no significant external signs of injury, and could be observed reliably with physical examination.

PCT was defined as a protocol of noncontrasted scans of the head and cervical spine followed by CT scans of the thorax, abdomen, and pelvis with intravenous contrast. SCT was defined as scans limited to body regions with abnormal clinical findings. All cost, incidence, and utility values used in this study were obtained from values in the available literature.

Decision software (TreeAge Pro Healthcare Module 2011; TreeAge Software, Inc., Williamstown, MA) was used to construct a state transition Markov decision model (Fig. 1) to analyze the components of the decisions, potential consequences, and probable outcomes. This model compared PCT with SCT with a 1-year cycle time frame to capture the initial trauma evaluation, hospital stay, and rehabilitation in patients who sustained injuries. The analytic horizon included the life span of the otherwise healthy 30-year-old males whose life expectancy was 80 years,¹¹ translating to 50 Markovian cycles after which all states reached death.

All patients received either a PCT or an SCT and were triaged according to CT findings. Patients with a normal PCT findings were observed in the emergency department (ED) for 8 hours and then discharged. Patients who received a negative SCT finding were admitted for 24 hours of observation. Patients who were found to have injuries on either PCT or SCT received a routine 2-day admission, consistent with the average length of stay from studies of patients with injuries of similar severity.^{12,13} Admitted patients were discharged home if they had no occult injuries. Patients with occult injuries were further stratified into critical and noncritical groups, as a delay in diagnosis of crucial missed injuries has the potential of becoming a severe problem.¹⁴

All patients were subjected to a one-time dose of radiation from either PCT or SCT, which carried a lifetime risk of being diagnosed with cancer. PCT exposed patients to 30 mSv of radiation.¹⁵ SCT exposure was estimated at 18 mSv, as a

proportional decrease in CT use.¹⁶ Patients who developed RIC had higher mortality rates as well as added costs.¹⁷

Probability of Clinical Events

The incidence of abnormal findings on PCT was based on observations from a similar cohort of patients undergoing PCT. The incidences of occult injury, both critical and noncritical, in patients undergoing PCT were derived from observations by Salim et al.¹⁸ The incidence of positive selective CT scan findings was estimated based on rates reported in two publications. The first study looked at CT scanning in blunt trauma patients that were designated as “desired” or “undesired” by the trauma surgeon or ED physician. The desired CT scans identified abnormalities in 22% of the patients.¹⁹ The second report involved the use of PCT in patients following motorcycle collisions, and 45% of the PCTs identified abnormalities. The higher rate of abnormal findings was likely caused by a higher mean ISS in this study population.²⁰ The rate of abnormalities based on SCT was averaged and adjusted based on expert consensus, with appropriate minor adjustments made to account for an equal number of injuries in both the PCT and SCT groups. The incidence of occult injury in patients undergoing SCT was also obtained from the University of California Los Angeles study, where 10% of undesired scans contained an abnormality. The incidence of critical occult injury in SCT was derived from the percentage of patients with undesired scans who underwent a predefined critical action.¹⁹ The incidence of RIC in PCT and SCT were derived from a retrospective study describing radiation dose associated with various CT scans and extrapolating lifetime attributable cancer risk¹⁵ (Table 1).

Cost Determination

The cost of the initial treatment of trauma was taken from the median cost of studies reporting a lower average ISS.²¹ The cost of admission was estimated from the average cost of community hospital stay in the United States.²² Total hospital encounter costs for critical and noncritical occult injury were obtained from median costs of major and minor complications in a study of more than 500 trauma patients.²³ Cost of PCT was obtained from a cost analysis of whole-body CT screening estimated from public data.²⁴ The cost of SCT was estimated as a proportion decrease of PCT cost, which was derived from a study that compared liberal versus selective CT scanning.¹⁶ Initial, yearly, and final costs of RIC were estimated from a study estimating costs based on Surveillance, Epidemiology, and End Results Program data.¹⁷ All costs were converted into US 2010 dollars, discounted at a rate of 3% per year (Table 1).

Utility Determination

The utility of patients who underwent routine trauma admission with a positive PCT or SCT finding without evidence of occult injury was obtained from a study looking at the cost-effectiveness of treatment at a Level 1 trauma center. Quality-adjusted life-years (QALYs) were calculated using the SF-6D questionnaire, encompassing six dimensions of health as follows: physical function, role limitations, social function, pain, mental health, and vitality. The utility value was adjusted proportionally, given that our study had a different predefined baseline of 1.^{25,26} Utilities of patients who had negative PCT

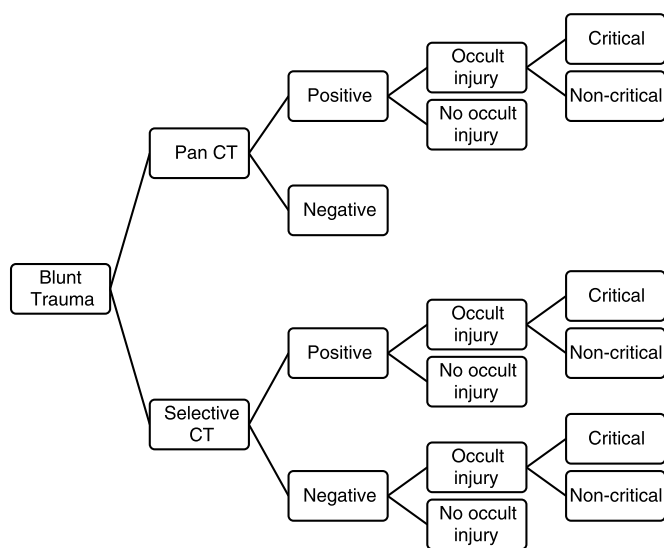


Figure 1. The decision tree.

TABLE 1. Costs, Incidences, and Utilities of Possible Outcomes

Variable	Value	Range	Reference
Cost of initial trauma care	\$12,598	\$9,449–\$15,748	Pooled estimate ²¹
Cost of PCT	\$1,174	\$881–\$1,468	Observational ²⁴
Cost of SCT	\$740	\$555–\$925	Observational* ¹⁶
Cost of ED observation	\$715	\$536–\$894	US Census ²²
Cost of 24-h admission for observation	\$1,909	\$1,432–\$2,386	US Census ²²
Cost of routine 2-d hospital admission	\$3,706	\$2,780–\$4,633	US Census ²²
Cost of care for critical occult injury	\$55,093	\$41,320–\$68,866	Observational ²³
Cost of care for noncritical occult injury	\$32,974	\$24,731–\$41,217	Observational ²³
Cost of cancer, first year	\$44,645	\$33,484–\$55,806	Pooled estimate ¹⁷
Cost of cancer, yearly	\$6,234	\$4,676–\$7,793	Pooled estimate ¹⁷
Cost of cancer, final year	\$134,235	\$100,676–\$167,794	Pooled estimate ¹⁷
Incidence of positive finding in PCT	35.20%	26.4–44%	Observational* ¹⁸
Incidence of positive finding in SCT	28.00%	21–35%	Pooled estimate* ^{19,20}
Incidence of occult injury in positive PCT finding	0.65%	0–1%	Observational* ¹⁸
Incidence of occult injury in positive SCT finding	10.00%	5–15%	Observational* ¹⁹
Incidence of occult injury in negative SCT finding	10.00%	5–15%	Observational* ¹⁹
Incidence of critical occult injury in PCT	33.00%	25–41%	Observational* ¹⁸
Incidence of critical occult injury in SCT	3.00%	0–6%	Observational* ¹⁹
Incidence of PCT lifetime RIC	0.10%	0–1%	Pooled estimate ¹⁵
Incidence of SCT lifetime RIC	0.06%	0–1%	Pooled estimate ¹⁵
Utility after ED discharge after negative PCT finding	0.99	0.9–0.99	NA**
Utility after observation after negative SCT finding	0.95	0.9–0.95	NA**
Utility after trauma admission after positive PCT finding	0.82	0.7–0.9	Pooled estimate ^{25,26}
Utility after noncritical occult injury	0.78	0.7–0.9	NA†
Utility after critical occult injury	0.75	0.65–0.85	Observational ²⁷
Utility after RIC	0.72	0.6–0.8	Pooled estimate ^{28,29}

*Denotes a prospective study.

**Estimated as minimal impact to first year utility from noninjury.

†Estimated utility as between routine admission and critical occult injury.

All costs converted to 2010 US dollar, discounted 3% annually.

NA, not applicable.

and SCT findings were estimated based on the assumption that observation after trauma without significant injury would have minimal impact on the first-year quality of life. The utility of patients after critical missed injury was assumed to be debilitated with a prolonged hospital course for the first year after injury, estimated from patients with traumatic spinal cord injuries.²⁷ The study used standard gamble utility scores, which were derived from the probability of dying from a hypothetical treatment that patients would be willing to undergo to improve their quality of life from their current state back to full health. The utility of patients with noncritical occult injuries was estimated to be between that of routine trauma admission without occult injury and that of critical occult injury. The utility of patients with RIC was estimated from patients with chronic myelogenous leukemia and from general public regarding soft tissue sarcoma.^{28,29} All utilities were discounted at a rate of 3% per year (Table 1).

Sensitivity Analysis

One-way and two-way sensitivity analyses were performed on all cost, incidence, and utility variables throughout the ranges listed in Table 1. These ranges were established based on the average values in the literature, either from observational studies or from pooled estimates. When no published

range was available, we used expert opinion and established ranges that were 25% above and below the mean value. The results of the model were defined to be sensitive to any particular variable if the recommendation changed for the corresponding range of individual variables. Monte Carlo simulation was performed to approximate the probability distribution by running 100,000 first-order trials. This estimates the sampling uncertainty in the model, and the results were reported as SDs.

Assumptions

Several assumptions were made during the construction of our analysis. (1) Patients who had a normal PCT finding were discharged home after an 8-hour ED observation and assumed to have no missed injuries. (2) Patients who had a positive PCT or SCT finding without occult injury were admitted for 2 days. (3) Patients who had a negative SCT finding without occult injury were admitted for observation for 1 day. (4) Patients are assumed to be healthy with a baseline utility of 1 before the trauma. There was no initial mortality from trauma. One year after the trauma, patients returned to their usual state of health and quality of life with a 3% annual discounted rate. (5) Patients who develop RIC have a fixed quality of life after their diagnosis, with a 3% annual discounted rate until their death. (6) The risks and costs of

TABLE 2. Expected Costs and Utility for PCT Versus SCT in Blunt Trauma

Intervention	Expected Cost, US dollar	Incremental Cost, US dollar	Expected Utility, QALY	Incremental QALY	Cost per Utility, US dollar	ICER
PCT	15,682.09	NA	26.422	NA	593.52	Dominant
SCT	17,673.28	1,991.19	26.396	-0.026	669.54	NA

ICER, incremental cost-effectiveness ratio; NA, not applicable.

incidentalomas and contrast-induced nephropathy resulting from CT scanning were not included in this analysis. (7) Productivity losses are not included in the analysis to calculate cost as the model is framed from a health care perspective, not a societal perspective. (8) Any subsequent CT scans that the patients may require as a result of their trauma are not included in this analysis, which only evaluates the initial decision of whether to proceed with PCT or SCT.

RESULTS

The overall cost per patient including the costs of the trauma activation, CT scans, posttrauma care, critical and non-critical occult injuries, and RIC was \$15,682 for the PCT strategy and \$17,673 for the SCT strategy. SCT had an excess cost of \$1,991 per patient in comparison with PCT. Patients discharged home with a negative PCT finding versus patients discharged home with a negative SCT finding and no occult injury had costs of \$14,567 and \$15,307, respectively. Patients with a noncritical occult injury had average costs of \$34,249 with the PCT strategy and \$33,774 with the SCT strategy. Those with critical occult injuries had costs of \$56,368 per patient undergoing PCT and \$55,893 per patient undergoing SCT.

There was no significant difference in QALYs between the PCT and SCT groups. The overall QALY for patients undergoing PCT was 26.42, compared with 26.40 for patients undergoing SCT. There was a cost savings of \$75 per QALY in patients receiving PCT versus SCT (\$594 per QALY vs. \$669 per QALY) (Table 2).

Monte Carlo Simulation

The total costs per patient for a simulation of 100,000 blunt injury patients undergoing PCT and SCT were \$15,687 and \$17,694, respectively. SDs for PCT and SCT were \$3,776

and \$6,297, respectively. The utilities for PCT and SCT were 26.42 and 26.40, respectively, with SDs less than 0.01 (Table 3).

Sensitivity Analysis

One-way sensitivity analysis did not reach threshold with variation of the cost, utility, and incidence of clinical events through our set ranges listed in Table 1. Two-way sensitivity analysis demonstrated that the incremental cost approached threshold when decreasing the cost of SCT scan to \$250 as well as cost of 24-hour observation to \$12,190 for patients with a negative SCT scan finding (Fig. 2). In addition, two-way analysis also demonstrated a shift toward equal cost-effectiveness between PCT and SCT only when the cost of ED observation following negative PCT finding was more than \$2,000 higher than the cost of admission for 24-hour observation for patients with negative SCT finding (Fig 3).

DISCUSSION

PCT is currently an integral component of the trauma evaluation. Several retrospective studies have demonstrated decreased morbidity and mortality in severe blunt trauma patients when PCT is part of the management protocol.¹⁻⁴ Increasingly used in hemodynamically stable patients with a moderate mechanism of injury, the PCT strategy is shown to rapidly identify injuries, many that may seem minor but have been shown to alter treatment in nearly a fifth of patients.¹⁸ To determine the cost-utility of PCT in this setting, we designed a Markov model to study the overall costs of care associated with either a PCT strategy or an SCT strategy. The model found that PCT resulted in a nearly \$2,000 savings per patient, without impacting QALYs, resulting in a \$75 savings per QALY.

The use of PCT in stable blunt trauma patients who had a moderate mechanism of injury, without significant external signs of injury, rapidly identifies injuries and allows patients to

TABLE 3. Monte Carlo Simulation, n = 100,000

	Cost, US dollar				
	Mean	SD	10%	90%	SQRT [Variance/Size]
PCT	15,686.80	3,775.62	14,466.58	17,478.36	11.94
SCT	17,693.78	6,297.38	15,246.95	33,714.00	19.914
	Utility, QALYs				
	Mean	SD	10%	90%	SQRT [Variance/Size]
PCT	26.42	0.35	26.32	26.49	0.001
SCT	26.40	0.27	26.28	26.45	0.001

SQRT, square root.

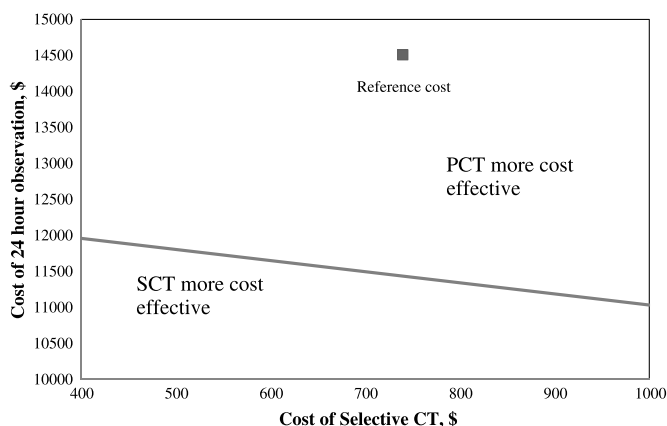


Figure 2. Two-way sensitivity analysis plot. Cost of SCT versus the cost of 24-hour observation. Line graph of relationship between the cost of SCT scan and the cost of 24-hour admission for observation, in US dollars. Line signifies threshold, above which PCT is more cost-effective and below which SCT is more cost-effective. Square marker signifies the reference costs used in this study.

be safely discharged without further observation.⁶ Recent prospective studies on stable trauma patients with minor injuries demonstrated the utility of PCT in identifying critical injuries that otherwise may have been missed. The University of Southern California group found that stable patients without obvious external signs of injury undergoing PCT had clinically significant abnormalities in 3.5% of head, 5.1% of cervical spine, 19.6% of chest, and 7.1% of abdominal CTs. Findings in 18.9% of these patients led to a change in treatment.¹⁸ In a similar study, the University of California Los Angeles group found an abnormality in 10% of CT scans, which at least one physician deemed unnecessary. Of 95 patients that had an abnormal undesired scan finding, 3 patients required a critical intervention.^{19,30} In addition, PCT may have a role in allowing busy trauma centers to triage patients and allocate resources effectively by identifying which patients can be safely discharged.

There are potential downsides to a PCT strategy including concerns about radiation exposure, unnecessary workup for incidentalomas, and contrast-induced nephropathy, which have significant costs and negative impact on patients' overall quality of life. CT scanning accounts for 75% of diagnostic radiation received by patients.³¹ Although the data on the incidence of cancer after CT scanning are extrapolated and may not be completely accurate, it is the best estimate currently available, and approximately 29,000 cancers per year are associated with CT scans in the United States.⁸ In a prospective cohort study, trauma patients receive an average of 22.7 mSv, which results in 190 cancer deaths in 100,000 exposed patients.⁹ The number of CT scans per trauma patient is increasing, especially in critically ill patients.^{32,33} These risks must be carefully weighed on a macroscopic level to minimize overall health care costs. However, in our model, despite the poor quality of life and high costs of care for patients who develop RIC, the rate of cancer development following a single PCT is low and does not offset the cost benefits of PCT.

Our cost-utility analysis found a cost savings of \$1,991 per patient when a PCT strategy was compared with an SCT plus observation approach, which in busy trauma centers can result in significant savings over time. There was no major difference in QALYs between the two groups, but a cost savings of \$75 per QALY for patients managed with PCT. In addition, the cost per QALY of both the PCT and the SCT approach was significantly below standard willingness-to-pay threshold of \$30,000 to \$50,000 per QALY used in many health care cost analyses.

Our sensitivity analyses show that even when accounting for changes in the cost, utility, and the incidence across our range of variables, cost-effectiveness was dominated by the PCT approach. Only by significantly decreasing the cost of both the SCT scan and 24 hours of observation did the margin of PCT effectiveness decrease toward threshold of equal cost-effectiveness. In addition, a change in cost-effectiveness occurred when decreasing the cost of 24-hour observation in patients with negative SCT findings and increasing the cost of ED observation in patients with negative PCT findings. Even then, the cost of care after negative SCT finding needs to be approximately \$2,000 less than that of the care after a negative PCT finding for this to be feasible.

There are several limitations to this study. The analysis is dependent on the available literature regarding the incidences and costs of the various outcomes. Because of the nature of this analysis, many of the variables have to be estimated based on existing data. Our sample population is a narrow subset of young, otherwise healthy patients without any variability and cannot be widely applied. Our analysis assumes that patients will return back to their baseline quality of life after 1 year; however, in reality, patients with severe occult injuries may never resume their baseline functions. Workup and treatment of incidentalomas and contrast-induced nephropathy were not included in our analysis and may contribute to additional costs and decreased quality of life to patients undergoing PCT,

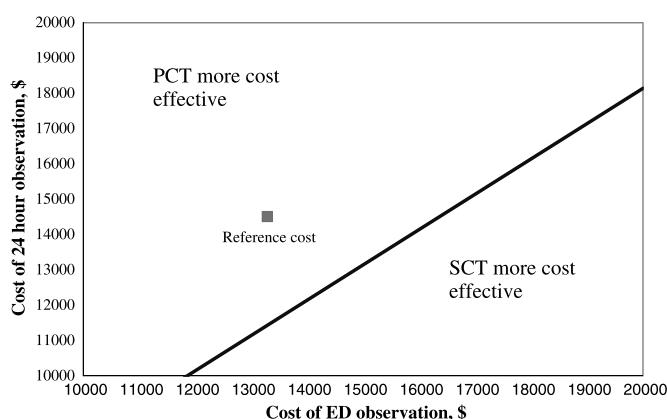


Figure 3. Two-way sensitivity analysis plot. Cost of ED observation versus the cost of 24-hour observation. Line graph of relationship between the cost of ED observation and the cost of 24-hour admission for observation, in US dollars. Line signifies threshold, above which PCT is more cost-effective and below which SCT is more cost-effective. Square marker signifies the reference costs used in this study.

although incidences are low particularly in this homogenous, young patient population. The decision to not include these additional variables was in an effort to keep the model as simple and therefore as reliable as possible. Finally, while our study assumes that all patients with negative PCT and SCT findings will be discharged home after appropriate observation, we acknowledge some may stay for reasons such as pain or social situations. Moreover, a small number of patients with a negative SCT finding may be discharged home without hospital admission by the attending trauma surgeon because of completely benign findings; adjusting for these minor changes in our sensitivity analysis did not offset the overall cost benefit of PCT.

Our findings suggest that a routine PCT strategy is cost-effective over the SCT strategy in patients with moderate mechanism of injury and without obvious external signs of injury. The cost-effectiveness of PCT is due to the low rates of missed injury, the ability to safely discharge uninjured patients from the ED without hospital admission, and the low rates of RIC. PCT in this patient group is cost-effective.

AUTHORSHIP

W.S.L., N.A.P., and T.H.L. contributed to the design of this study. W.S.L., N.A.P., and A.G. conducted the literature search. W.S.L. and A.G. collected the data, which A.G. analyzed. N.A.P. and T.H.L. contributed to data interpretation. W.S.L. and N.A.P. wrote the manuscript. N.A.P., B.J.A.P., T.H.L., and G.P.V. performed critical revision.

DISCLOSURE

The authors declare no conflicts of interest.

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DISCUSSION

Dr. Samir M. Fakhry (Charleston, South Carolina): I would like to congratulate the authors on this well-designed analysis of the cost utility of pan CT versus selective CT. But it was for a very select sub-group of patients: 30-year-old males without visible injuries and with normal mental status. Note that this is a severe limiting in its application to other cohorts.

Use of Markov modeling and simulation with inputs derived from mildly accepted sources is well thought out and state-of-the-art and it also sounded really cool to me because I didn't think of that. Overall, this study supports my personal bias, that more CT scan use coupled with shorter time in the hospital is cost-effective.

First, I remain very concerned about the issue of false negative CT scans given that the false negative rate of about 6% has been quoted for Pan CT (PCT), which could be higher or lower at different centers with different expertise, and the serious consequences of some of the uncommon but serious

injuries you can miss such as bowel injuries or blunt cervical/vascular injury.

I would be concerned that the less experienced practitioner would use your data to justify large-scale PCT with subsequent discharge home without consideration of the statistically low but very serious injuries mentioned. I am already worried that my residents are now making hundreds of photocopies of your abstract and putting them up on the wall. So can you provide us with a way to incorporate that information?

My second question is—I am not an expert in Markov modeling so please take this question with that caveat—you chose to analyze cost-effectiveness with this highly-homogenous cohort. We don't usually see that in real clinical life.

Could you use a Markov model with heterogeneous cohorts using techniques of random walk or micro-simulation that would vary the clinical characteristics and outcomes of the patients and then allow us to apply that to a more heterogeneous cohort?

Dr. Wayne S. Lee (San Francisco, California): Thank you, Dr. Fakhry, for those questions. For your first question regarding the false-negative rate of the CT scans, that is included in our analysis for the missed injuries and we separated that into critical and not-critical occult injuries.

The hollow viscus injuries and blunt injuries to the bowel is the Achilles heel of PCT scan and does require additional observation. And, fortunately for those patients, it's a very rare event. And unfortunately it is something that can happen.

These patients in our model do undergo eight hours of observation in the PCT strategy group that have a negative PCT. So there is no good way to treat these patients with hollow viscus injuries. However, in terms of our cost analysis we're just looking at this homogenous group of patients between PCT and selective CT strategy.

For the second question about whether or not we can apply a Markov model to a heterogeneous cohort, I think it is possible. We would just have to change our values around to be able to extend the applicability. And definitely from our analysis, you would have to use a lot of judgment in applying that to a different group of patients.