#### A Comparison between Surgical Tracheostomy and Percutaneous Tracheostomy in Critically ill Patients

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Abstract: Background and Objectives: Percutaneous dilatational tracheostomy (PDT) had largely replaced surgical tracheostomy in the intensive care unit setting. Although it seems logical that surgeons continue to do tracheostomies, anesthesiologists and intensive care specialists are familiar with airway control and guide wire techniques and could replace surgeons in the performance of PDT. Percutaneous dilatational tracheostomy might reduce the number of complications in Egyptian patients. Thus, this study aims to compare between ST and the PDT concerning the outcome and the complications (Intra and early post-operative) in critically ill patients. Study design: this is a randomized single-centre control study was prospectively conducted on 60 critically ill patients who were scheduled to do tracheostomy in the period from January 2010 to January 2011. Patients were divided into two groups: The surgical tracheostomy (ST) group 30 patients and the percutaneous dilatational tracheostomy (PDT) group 30 patients. All the demographic, intra-operative and postoperative data were prospectively collected and analyzed statistically. The patients were followed for one week post-operative. Results: there was no significant difference between both groups concerning the baseline demographic data, the ICU admission diagnosis, the co-morbidities and the intra-operative complications but the early post-operative complications were significantly higher in the ST group compared to the PDT group. The duration of ICU stay and mechanical ventilation days were significantly higher in the ST compared to the PDT group Conclusions: there was a higher incidence in the early postoperative complications and mortality in the ST group compared to the PDT group in critically ill Egyptian patients. Hence, PDT could be the procedure of choice for the management of the airway in critically ill patients provided there is a good experience.

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Key word: Surgical tracheostomy, Percutaneous tracheostomy, Critical care

Abbreviations: ST = surgical tracheostomy; PDT = Percutaneous dilatational tracheostomy; ICU = Intensive care unit

#### 1. Introduction

Tracheostomy is becoming a very common procedure in the ICU, with improvements in critical care medicine over the past 30 years; more patients are surviving initial episodes of acute respiratory failure, trauma, and extensive surgeries and are requiring prolonged periods of mechanical ventilation. It is now common practice to expeditiously convert these patients from translaryngeal intubation to tracheostomy (*Epstein ,2005*).

Most surgeons prefer the operating room (OR) for the formation of tracheostomy. Unfortunately, the risks of transporting critically ill patients from the ICU may result in increased morbidity Moreover, the dependency on surgeons, inability to get (OR) time, and other emergencies may delay elective tracheostomy in patients requiring intensive care (Smith et al., 1990). Tracheostomy as a surgical procedure reputedly dates back to Egypt some 3500 years ago. The standard tracheostomy technique was described in 1909 by (Jackson, 1909). Thus in this study it was our aim to compare the standard surgical tracheostomy technique and the percutaneous dilatational tracheostomy technique (PDT) using the Ciaglia technique as regard the complications, and the outcome in critically ill patients.

#### 2. Patients & Methods: Study Design:

This is a randomized study was prospectively conducted on sixty patients who underwent tracheostomy at the Critical Care Medicine Department., at Cairo University Hospitals, Egypt in the period from January 2010 to January 2011. Informed written consents had been obtained from the relatives and the study was approved by the Hospital's Ethics Committee.

Eligibility criteria for patients included in this study were Prolonged ventilatory support, Airway control, Pulmonary toilet, Airway obstruction, and Have signed the informed written consent (patients legal representative). This study excluded patients with the following criteria: Infection of tracheostomy site, Known or expected difficult endotracheal intubation, distorted anatomy with unidentifiable anatomic land marks, previous surgery at the site, bleeding diathesis, unstable cervical spine and refusal to sign the informed consent

# Patient's selection and classification:

During the period from January 2010 to January 2011, sixty five Critical care patients who scheduled

for tracheostomy were screened for enrollment. Of these, five patients were excluded, because they had one or more reason for exclusion. **Sixty patients were randomly assigned into two groups** surgical tracheostomy (ST) group 30 patients and Percutaneous dilatational tracheostomy (PDT) group 30 patients For every patient the Preoperative data as personal history, clinical examination, presence of co-morbid conditions Duration of intubation in days were collected.

### Surgical techniques and procedure:

#### Preparation of the patient

In both the surgical and percutaneous techniques the anticoagulant was stopped at least 12 hours before the procedure or after correction of coagulopathy when indicated. Patients were placed on a regimen of 1.0 FIO<sub>2</sub>, and analgesia, sedation and relaxation were administered. The neck was hyperextended (unless the patient requires cervical spine precautions) and antiseptic solution on the surgical field was administered (**Durbin**, 2005). All patients were monitored for ECG, respiratory rate, arterial blood pressure and pulse oximetry.

#### (A) Open surgical technique

A 2–3 cm vertical or horizontal skin incision was made midway between the sternal notch and thyroid cartilage (approximate level of the second tracheal ring *(Cameron,2008).* After division of the skin and underlying platysma, blunt dissection is continued longitudinally. Separation of the strap muscles (i.e., sternothyroid, sternohyoid) and lateral retraction exposes the trachea and overlying thyroid isthmus.

The isthmus may be mobilized and retracted superiorly or divided (*Scott-Conner*, 2002). Nearby vessels can bleed substantially, and hemostasis is achieved with and the second to fifth anterior tracheal rings can be visualized. A cricoid hook can provide upward traction on the trachea, thereby improving exposure.

Lateral tracheal stay sutures at the third or fourth tracheal rings can provide lateral traction and stabilization and help to define the stoma (*Jackson*, *1909*). Once hemostasis and exposure are optimized, the trachea is opened vertically or transversely with a scalpel (*Scott-Conner*, *2002*). A distally based tracheal-wall flap (Bjork flap) may be created or a section of the anterior tracheal wall removed. Pole retractors in the stoma maintain patency, and the endotracheal tube is withdrawn under direct vision. A suction catheter placed into the open airway can be used as a guide for tracheostomy tube insertion. Correct placement is confirmed by direct visualization, ease of ventilation and adequate oxygen saturation (*Scott-Conner*, *2002*).

### (B) <u>The percutaneous technique</u>

Ciaglia technique was performed using the Ciaglia multiple dilator kit (Ciaglia Percutaneous Tracheostomy Introducer Set; William Cook Europe, Bjaeverskov, Denmark).

The endotracheal tube was repositioned above the site of the proposed tracheostomy. The endotracheal tube cuff will be deflated and it will be withdrawn to just below the vocal cords by an assistant. After that the assistant holding the tube with his or her hands continuously throughout the whole procedure. Blood pressure, cardiac rhythm and arterial hemoglobin saturation will be continuously monitored through the procedure.

The cricoid is palpated and a 2-cm transverse skin incision made at the level of the second tracheal ring. Blunt vertical dissection is followed by tracheal puncture with a 22-gauge seeker needle followed by an adjacent 14-gauge needle connected to a saline-filled syringe (*Durbin, 2005*). Aspiration of bubbles suggests appropriate tracheal puncture.

This leads to guide wire insertion followed by needle removal. According to their original descriptions, the Ciaglia technique uses sequential tracheal dilators (Cook Critical Care Inc.) over the guide wire (*Ciaglia et al., 1985*)

# All patients were evaluated during and after the procedure and the following data were recorded:

- 1) The intra and post operative complications (Bleeding, Hypoxia, Hypotension, Pneumothorax, Surgical emphysema, false passage, Inability to complete the procedure, Procedural mortality, wound infection and atelectasis.
- 2) ABG, Chest x ray, Hb level, Mean Arterial blood pressure, the duration of the procedure (Minutes), the duration of ICU stay (days), the duration of mechanical ventilation (days). The number of patients who were successfully weaned from mechanical ventilation after tracheostomy, the outcome (death, discharge).

Study End points: Death, complications . discharge.

# Data Analysis:

All data were collected prospectively. Categorical data are displayed as percentages. Continuous data are reported as mean±SD. Comparisons were performed with an unpaired *t* test for continuous, normally distributed data. Comparisons between categorical variables were performed with Chi-square  $X^2$  test. P < 0.05 was considered as significant. SPSS (version 13) software was used for data analysis.

# 3. Results

# 1) Demographic data:

The baseline demographic characteristics were homogenous in the two groups without statistical

significant difference (p < 0.001) concerning number, age; sex Table (1). Regarding the skin incision size, it was significantly longer in the ST group compared to the PDT group ( $3.42 \pm 0.56$  vs  $1.72 \pm 0.29$ ). The APACHE II score was significantly higher (p

<0.001)in the ST group compared to the PDT group( 29.50 (26-34) vs. 20 (16-26).

(2) Diagnosis on Intensive Care Unit (ICU) admission There were no significant differences between both groups regarding the diagnosis on ICU admission (Table -2).

Table (1): The baseline demographic characteristics of both group
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	ST	PDT	Test of sig.
Number of patients	30	30	
Age (years) median (range)	54 (22-76)	52 (23-72)	Z = 0.400 p = 0.689
Sex(n) male/female	17 (56.7%)/13(43.3%)	11(36.7)/19(63.3)	=2.411 p = 0.121
Skin incision size (cm)	$3.42 \pm 0.56$	$1.72 \pm 0.29$	t=14.834 p <0.001*
APACHEII score median (range)	29.50 (26-34)	20 (16-26)	p <0.001*

PDT: Percutaneous Dilatational Tracheostomy.APACHE II: Acute Physiology and Chronic Health Evaluation . NS: not significant. ST: surgical tracheostomy

Z: Z for Mann Whitney test  $\chi^2$ : Chi square test t: Student t-test P: Statistically significant at  $p \le 0.05$ 

	ST N=30			PCT N=30
	No	%	No	%
Cerebrovascular disease	10	33.3	12	40.0
Cancer patient (Complicated)	3	10.0	3	10.0
Post- cardiac arrest	2	6.7	3	10.0
Post operative	2	6.7	2	6.7
Decompansated heart failure	4	13.3	3	10.0
Respiratory failure (all types)	6	20.0	5	16.7
Renal failure	1	3.3	1	3.3
Neuromuscular disease	2	6.7	1	3.3
Total	30	100.0	30	100.0
МСр	0.995			

#### (3) Indications for tracheostomy:

There were no significant difference between both groups regarding the indications for tracheostomy (Table -3)

#### Table(3): Indications of Tracheostomy

	S N =	T = 30	PI N=	-	МСр
	No	%	No	%	
Hypoxic brain damage with coma	2	6.7	4	13.3	
Sepsis with multi-organ failure (MOF)	6	20.0	5	16.7	
Upper airway obstruction (e.g tumor)	3	10.0	0	0.0	
Chronic obstructive lung disease	2	6.7	1	3.3	0.474
Acute respiratory distress syndrome	4	13.3	5	16.7	
Cerebrovascular disease	10	33.3	8	26.7	
Difficult weaning from MV*	3	10.0	7	23.3	
Total	30	100.0	30	100.0	

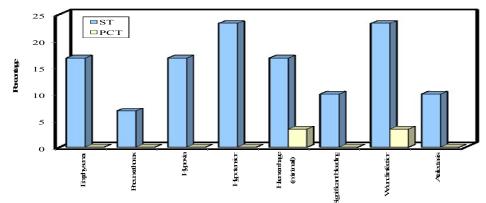
V\*: Mechanical ventilation MCp: p for Monte Carlo test

\*: Statistically significant at  $p \le 0.05$ 

#### (4) Complications of tracheostomy in both groups:

In the present study there was no statistically significant difference between both groups regarding the intra-operative complications of tracheostomy but the rate of complications in the early postoperative period (within one week) was significantly higher in the ST group compared to the PCT group: **surgical emphysema** [(5 patients (16.7%) vs none (*P*: 0.052)),

**pneumothorax** (2 patients (6.7%) vs none (P: 0.492), **hypoxia** (5 patients (16.7%) vs none (P: 0.052), **wound infection** (7 patients (23.3%) vs 1 patient (3.3%) (P: 0.053), **minimal bleeding** (5 patients (16.7%) vs 1 patient 3.3% (P: 0.195), **significant**  **bleeding** (3 patients (10.3%) vs none (P: 0.293), **postoperative hypotension** (3 patients (10.3%) vs none (P: 0.293)) and **postoperative collapse** (3 patients (10.3%) vs none (P: 0.293)) in the ST group compared to the PDT group (Fig. 1).



#### Figure (1): Complications of tracheostomy in surgical and PDT groups (postoperative)

#### 5) Prognostic factors post tracheostomy

As shown in (Table 4), the mechanical ventilation days was significantly higher in the ST group compared to the PDT group  $(24.77 \pm 2.71 \text{ vs } 11.67 \pm 1.63)(p \text{ value of } 0.0001)$ . Also the mean duration of ICU stay in the PDT group  $(18.07 \pm 2.57)$  was significantly shorter than that of the surgical group ( $30.67 \pm 2.80$ , P < 0.001).

Regarding duration of endotracheal intubation (ETT) we found the ETT days was significantly higher in ST compared to the PDT group (p < 0.001), also the mean duration of the procedure was significantly longer (P < 0.001) in the ST group compared to the PDT group (34.10±7.46 vs 7.63±2.24).

Cable-4 Prognostic factors post tracheostomy										
	ST N = 30		PDT N=30		Z(P)					
	Mean	SD	Mean	SD						
Mechanical ventilation days	24.77	2.71	11.67	1.63	6.679* (<0.001)					
ICU days	30.67	2.80	18.07	2.57	6.681* (<0.001)					
Endotracheal intubation days	20.77	2.11	9.33	1.30	6.696* (<0.001)					
Procedural time (min)	34.10	7.46	7.63	2.24	6.222* (<0.001)					

Z: Z for Mann Whitney test \*: Statistically significant at  $p \le 0.05$ 

# 6) Weaning from mechanical ventilation (MV) after tracheostomy

As shown in table -5 the number of patients who were successfully weaned from MV after tracheostomy

was significantly higher(P : 0.015) in the PDT group compared to the ST group (12.0 vs 3.0).

# Table-5 Comparing the ST and PDT groups regarding the number of patients who successfully weaned From MV after tracheostomy.

Fep	PDT N=30		ST N= 30		
-	%	No	%	No	
0.015*	40.0	12	10.0	3	- Number of patients who successfully weaned From MV after tracheostomy (n) (%)

FEp: p value for Fisher Exact test

\*: Statistically significant at  $p \le 0.05$ 

#### 7) The outcome of the patients in both groups

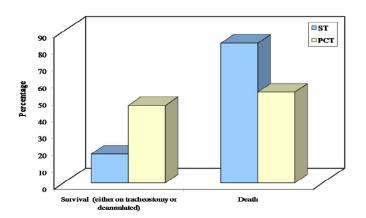
As shown in table-6 the mortality rate was significantly higher in the ST group compared to the PDT group 25(83%) vs 16(54%) (P: 0.025)

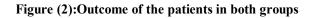
Fep	PDT N=30		ST N=30							
	%	No	%	No						
0.025*	46%	14	17%	5	-Surviva	al (either on	tracheostom	y or decann	ulated)	
- Death						25	83%	16	54%	

#### Table – 6 Outcome of the patients in both groups

\*: Statistically significant at  $p \le 0.05$ 

FEp: p value for Fisher Exact test





#### 4. Discussion

The modern era of percutaneous dilational tracheostomy (PDT) began in 1985, when *ciaglia* introduced a percutaneous tracheostomy procedure that used an easy and straight forward seldinger technique with progressive dilatation. During past two decades, performance of PDT has increased considerably with development of other techniques like *Griggs* technique (*Karvandian et al., 2009*).

In our study, the baseline demographic characteristics, diagnosis on Intensive Care Unit (ICU) admission, indications of tracheostomy and co-morbidities were homogenous between both groups without statistical significant difference. This was in agreement with (*Freeman et al.*,2000, *Turkmen et al.*, 2008; Karvandian et al.,2009).

In our study, there was no mortality related to either procedure. The PDT was not associated with clinically important hemorrhage (blood loss requiring blood transfusion or surgical intervention), purulent infection at the stoma, or any lethal complication.

The ST group had the following complications after return from the operating room; 3 patients had clinically significant bleeding and required blood transfusion, 5 patients had a minimal bleeding, 5 patients had surgical emphysema which resolved spontaneously, 2 patients with pneumothorax which had been resolved following chest tube drainage,3 patients had atalectasis of one or both lungs, 5 patients were hypoxic and 7 patients were hypotensive which may be due to problems attributed to the transport and 7 patients with stomal infection ( within 1 week) which may had been potentiated by the wide spread tissue dissection required for the surgical technique.

This in agreement with (*Turkmen et al., 2008*) who compared the complications in 30 critical care patients (15 in each group). Similarly there was no death related to the procedure, the procedure was successful in all patients. The PDT was not associated with clinically significant hemorrhage, purulent infection at the stoma, or any lethal complication. The ST group had 3 patients with stomal infection but no patient suffered pneumothorax, surgical emphysema, hypotension, hypoxia and clinically significant bleeding.

**Delaney et al., 2006,** conducted a research to systematically review and quantitatively analyze all randomized clinical trials (RCTs), comparing elective percutaneous dilatational tracheostomy (PDT) and surgical tracheostomy (ST) in adult critically ill patients with regards to major short and long term outcomes .Seventeen RCTs involving 1,212 patients were included. This systematic review and metaanalysis had demonstrated that the technique of PDT has a number of important advantages over performing a ST in critically ill patients who require an elective tracheostomy.

In consistent with our study (*Delaney et al.*, **2006**) found that PDT was associated with a reduction in the incidence of clinically important wound

infections compared with traditional ST, also similar to our study, there was no evidence that PDT resulted in an increased incidence of clinically significant bleeding, major peri-procedural or long term complications.

In the contrast to our study (*Dulguerov et al.,1999*) in a meta analysis showed an increase in prerioperative complications (10% versus 3%), perioperative death (0.44% versus 0.03%) and serious cardiorespiratory events (0.33% versus 0.06%) in the PDT compared to ST .In agreement with our study, the postoperative complications were more common for ST (10% versus 7%).

An important finding in our study, which is at variance with many reports, is that the mean duration of translaryngeal intubation before tracheostomy in the percutaneous group i.e (timing of tracheostomy) ( $10 \pm 2$ ) was significantly shorter than that in the surgical group ( $22 \pm 4$ ). This could be explained by the fact that the waiting period between making the decision to perform a tracheostomy and its actual performance is considerably shorter for PDT than ST because operating room availability is not a factor. In addition PDT does not require shifting of potentially unstable patients from the ICU to the operating room.

Consistent to our results there are only two studies (*Gysin et al.,1999*) they examined the time taken from the decision to perform a tracheostomy to the procedure being performed. Both found a significantly shorter time when the tracheostomies were performed using the PDT method. This may have additional implications for critically ill patients, including decreased duration of sedation, earlier weaning from mechanical ventilation and shorter overall length of stay in ICU.

# Many reports are consistent with our results and favor early tracheostomy

**Teoh et al. (2001)** found that patients with blunt, multiple organ trauma have a shorter duration of mechanical ventilation, fewer episodes of nosocomial pneumonia, and a significant reduction in hospital costs when the tracheostomy is performed within 1 week of their injuries. Similar benefits have been reported in patients with head trauma and poor Glasgow Coma Score, and patients with thermal injury, if a tracheostomy is performed within a week after the injury.

In our study, the mean duration of mechanical ventilation in the PDT group ( $12 \pm 3$ ) was significally shorter than that of the surgical group ( $25\pm 5$ ) this could be attributed to earlier application of the tracheostomy in the former group. This was comparable to many reports, *(Rumbark et al.,2004)* found that the early group had significantly decreased the duration of mechanical ventilation (7.6 versus 17.4 days).

Consistent to our study (*Griffiths et al.,2005*) who found that early tracheostomy (less than seven days) was associated with a shorter duration of mechanical ventilation; The combined results showed duration of artificial ventilation was significantly lower in the early tracheostomy group (weighted mean difference – 8.5 days, 95% confidence interval – 15.3 days to – 1.7 days, P = 0.03). Similarly (*Scales et al., 2008*) found that patients who had early tracheostomy had more ventilator-free days.

In our study, the mean duration of ICU stay in the PDT group  $(20 \pm 5)$  was significantly shorter than that of the surgical group  $(30 \pm 5)$  this could be attributed to earlier application of the tracheostomy in the former group. This was comparable to many reports, *(Rumbark et al. ,2004)* found that the early group had significantly decreased the duration of ICU stay (4.8 versus 16.2 days).

Consistent to our study (*Griffiths et al.,2005*) who found that the length of stay in the ICU was significantly lower in the early tracheostomy group ( 6.1 versus 15.3 days, P = 0.001). Similarly (*Marcus et al., 2010*), compared outcomes in 147 patients who had undergone a bedside tracheostomy. In 20 cases, the procedure was performed less than seven days after intubation. The rest 127 patient received the tracheotomy seven or more days later. They found that early tracheostomy can significantly shorten a patient's length of ICU stay.

In the present study, the mortality in the PDT group(16 patients) (54%) was lower than the ST group (25 patients) (83%). This could be attributed to : (a) earlier application of tracheostomy in the PDT group and thus avoiding complications of prolonged intubation, (b) avoiding the complications of the transport of critically ill patients to the operating room (c) the decrease in the amount of sedations and muscle relaxants given to the patient in the PCT group due to shorter time of the procedure.

This was in agreement with many reports;( *Rumbak et al.,2004*) reported that the early tracheostomy was associated with decreased mortality (31.7 versus 61.7 percent). Many other reports support our finding (*Saffle et al.,2002, Higgins et al.,2003 Bouderka et al.,2004*).

In our study, The mean duration of the procedure was significantly shorter in the PDT group compared to the ST group ( $8\pm 4 \text{ vs } 36\pm 10 \text{ minute}$ ). This was consistent with many reports , (*Karvandian et al.,2009*) found that the mean duration of the procedure in the PDT group was significantly shorter than the ST group ( $32 \pm 14.9 \text{ vs } 47 \pm 21.2$ ). *Holdgaard et al., 1998* found that the median time for insertion of the tracheostomy tube was 11.5 min (range 7-24 min) in the PCT group and 15 min (range 5- 47 min) in the ST group (P<0.01).

In our study, there was no stastically significant difference between both groups regarding the effect of tracheostomy on arterial blood gases, haemoglobin level, before and after tracheostomy, and coagulation profile before tracheostomy

Auzinger et al.(2007) studied the safety of PDT performed by experienced operators in 60 critically ill patients with liver disease and coagulopathy, they found that refractory coagulopathy ( defined as a platelet count of less than  $50 \times 10^9$  cells/L or an international normalized ratio (INR) of greater than or equal to 1.5 or a combination of both on the day of PDT and over the consecutive 3 days following PCT despite platelet transfusion and fresh frozen plasma ) associated with liver disease is not a contraindication for PDT.

In our study, the number of patients who were successfully weaned from mechanical ventilation (MV) was significantly higher in the PDT group compared to the ST group (12 vs 3), this may be attributed to earlier application of tracheostomy in the PDT group avoiding the unnecessary delay together with less inta-operative and immediate post-operative complications and other complications related to the transport in the PCT group compared to the ST group.

This was in agreement with (*Gatti et al.*,2004) who conducted prospective analysis over 33 patients to determine the predictors of weaning from MV after cardiac operation with the percutaneous dilatational tracheostomy (PDT). The early group was performed after a mean time of  $7.7 \pm 5.0$  consecutive days of translaryngeal intubation.

Twenty-four (73%) patients were weaned from ventilator after a mean time of mechanical ventilation of  $15.8\pm 9.1$  days. Time point of PDT was the only predictor of ventilator weaning (P=0.0029): there was significant association between PDT performed before the seventh consecutive day of translaryngeal intubation (early PDT) and successful weaning from MV (P=0.01; odds ratio=11.2, 95% confidence interval=1.2-104.3). Many other reports were consistent with our results (*Zagli et al., 2010; Bouderka et al.,2004)*.

# Conclusions

• The PDT is safe, effective, and can be performed at the bedside in the ICU so it does not require shifting of potentially unstable patients from the ICU to the operating room which is some times very risky and carries high rate of serious complications like hypoxia, hypotension, tube dislodgment, atelectesis, and cardiac arrest. Percutaneous tracheostomy (PCT) reduces the overall incidence of wound infection and may further reduce clinically relevant bleeding and mortality when compared with surgical tracheostomy (ST) performed in the operating theatre.

• The PDT procedure time is shorter than that for ST and the benefits include less an anesthesia or sedation time that can be reflected on the mean duration of translaryngeal intubation in the PDT group that was significantly shorter than the ST group. In addition The mean duration of mechanical ventilation and ICU stay in the PDT group was significantly shorter than that of the ST group.

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12/20/11

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