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Is intraparum suctioning is safe in newborn born to mother with meconium stain amniotic liquor: Randomized control trial

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***Abstract*---**Background: Meconium aspiration syndrome (MAS) is a life-threatening respiratory disorder in infants born through meconium-stained amniotic fluid (MSAF). Although anecdotal data concerning the efficacy of intrapartum oropharyngeal and nasopharyngeal suctioning of MSAF are conflicting, the procedure is widely used. We aimed to assess the effectiveness of intrapartum suctioning for the prevention of MAS. Methods: We designed a prospective quasi randomized control trial, assessor blind, single centre study. 312 patients with MSAF of any consistency, gestational age at least 37 weeks, and cephalic presentation were randomly assigned to suctioning of the oropharynx and nasopharynx (including the hypopharynx) before delivery of the shoulders (n=127), or no suctioning before delivery (n=185). Postnatal delivery-room management followed Neonatal Resuscitation Program guidelines. The primary outcome was incidence of MAS. Clinicians diagnosing the syndrome and designating other study outcomes were masked to group assignment. An informed consent waiver was used. Findings: No significant difference between treatment groups was seen in the incidence of MAS (36 [26.7%] suction *vs* 36 [19.5%] no suction; p=0.167),mortality in suction (5 [3.91%] *vs no suction(* 5 [2.74%];

p=0.779,) or in the duration of ventilation, oxygen treatment, and hospital care. There was statistically significant difference in need for mechanical ventilation for MAS (13 [10.23%] *vs* 4 [2.2%]; p=0.005), any respiratory support for MAS (25[19.7%]suction vs 18[9.7] p=.019). Interpretation: Routine intrapartum suctioning of infants born through MSAF does not reduce the incidence of MAS. On the contrary, intrapartum suctioning might result in complications like more infant required neonatal resuscitation and respiratory support.

***Keywords*---**intraparum suctioning, newborn, mother, meconium stain amniotic liquor.

Introduction

The term meconium is from the Greek word "meconium – arion"[1], meaning opium like. Aristotle gave the substance this appellation as he believed it induced fetal sleep. Meconium[2-4] is a viscous green liquid that consist of gastrointestinal secretions; bile, bile acid, mucus, pancreatic juice, cellular debris, amniotic fluid and swallowed vernix caseosa, lanugo and blood. The substance may first be found in fetal gastrointestinal tract between 10th to 16th weeks of gestation[1,3]. At birth from 16 to 200 gm of meconium may be passed by fullterm neonate. For most infants, passage of meconium likely represents maturational event. Meconium passage is rare before 37 weeks of gestation, but may occur in 35 % or more pregnancies lasting longer than 40 weeks[4-7].

In most reports,[8-14] the frequency of MSAF has ranged from 5.6% to 24.6% (median 14%). MAS has occurred in 1.7% to 35.8% (median 10.5%) of infants born through MSAF[8-12,15-23]. Of those infants who developed MAS, *7.3%* to 35% (median 17%) had been born though thin-consistency MSAF[12,19-21,24-26]. Death occurred in 4.9% to 37% (median 12%) of infants with MAS [10,12,14,16,18,22,25-27]. Passage of meconium has been often used as a marker of antepartum or intrapartum asphyxia . The hypothesis is that in utero hypoxia causes increased intestinal peristalsis and relaxed anal sphincter tone , resulting in meconium passage[28-30] . By contrast several author concluded that meconium passage does not independently correlate with fetal distress.[4,31]

In the 1970s and 1980s , people were influenced by the "biblical references" of Gregory et al[32], Ting and Brady[33], Carson et al[28] whose work led to widespread practice of postnatal intubation and intratracheal suctioning of meconium stained infants. Seemingly, with adequate oropharyngeal suction of infant by obstetrician as well as postnatal intubation and intratracheal suctioning the meconium aspiration syndrome (MAS) could be prevented. Carson[28] has claimed that, MAS should be virtually nonexistent when these procedures are followed. Before these recommendation for active cleansing of airways of infant born through MSAF as many as 62 % of such infants manifested with respiratory illness.

The first study to report on intrapartum suctioning was undertaken by Carson et al in 1976[28]. They published a study aimed at evaluated a group of 273 infants managed with the combined approach consist of intrapartum suction before

delivery of shoulders, laryngoscopy, and intubation when meconium was visualized at the level of vocal cords. They compared this cohort with the historical control group in which no intrapartum suctioning had been performed. The patient managed with this combined approach had lower incidence of MAS (1 out of 273 [0.4%] vs. 18 out of 947 [1.9%]). Although these differences did not reach statistical significance [p= 0.071], the authors suggested that a combined approach of intrapartum and post natal suction of the oropharynx and large airways decrease the risk of meconium aspiration syndrome and mortality in this group of infants.

Subsequent studies that looked specifically at intrapartum suctioning reported different results.[34-37] Falciglia et al.[34.35] reported results that were contrary to the findings by Carson et al. First, in a retrospective analysis of morbidity and mortality data of patients born through MSAF, the authors reported that the timing of suction (i.e. whether the suction was performed before or after delivery of the chest) did not influence the presence of meconium below the vocal cords.[34] Second, in a prospective observational study, the same authors reported that early (before delivery of the shoulders) ONPS at the perineum did not affect the rate of MAS.[35]Moreover, in the early ONPS group, 35% of the infants with MAS developed tension pneumothorax requiring chest drain .

Wiswell et al.[36] reported that when ONPS was not performed before delivery of the shoulders, neonates were more likely to develop MAS. Actually Wiswell et al study was done to see effect endotracheal suctioning in vigours baby for prevention of meconium aspiration syndrome There oropharangeal and nasopharyngeal suctioning was not a primary objective fir this study . there distribution of suctioning and not suctioning also unequal i.e. Suction done in 2000 babies and not done only 90 babies. Recently, Vain et al.,[37] in a large, multicenter, randomized study, reported that routine intrapartum oropharyngeal and nasopharyngeal suctioning of term infants born through MSAF does not prevent MAS. There were also no differences in subgroups of patients known to be at high risk of developing MAS. The subgroups included those with thick MSAF, abnormal fetal heart rate during labor, and those requiring extensive resuscitation in the delivery room. The study by Vain et al is the only large, randomized, clinical trial that has looked at intrapartum suctioning.

It can be concluded that routine intrapartum suctioning of infants born through MSAF does not reduce the incidence of meconium below the cords or the incidence of MAS. On the contrary, intrapartum suctioning might result in complications like pneumothoraces. Based on these results and current recommendation by AAP through the neonatal resuscitation programme, the international Liaison committee on resuscitation (ILCOR), and the ACOG, intrapartum management of these pregnancies has radically changed. Intrapartum suction of infants with MSAF is not recommended anymore [38-40].

Despite the evidence & recommendations, some authors still recommend intrapartum suction, if there is MSAF, specially for infants born in communities with limited resources, on the feeling that “the procedure is simple & does not carry significant adverse effects”. they follow different strategy according to meconium consistency[41,42]. To base on feelings and assumptions such as a strong

assertion – that intrapartum suction may be different in low resources population – is a rather weak argument ; feelings and expert opinion considered level of evidence 5 . One study carried out in the French maternities found that almost half of the survey centers systematically performed oropharangeal suctioning before delivery of the shoulder and laryngoscopy in half of the newborns [43.] Another national survey to assess current delivery room approaches in infant born through MSAF in Argentina and evaluated the adherences to NRP/AAP recommendations in different center . They found that intrapartum suctioning , postnatal intubation & suctioning of vigorous infant with MSAF are still commonly performed , while in depressed newborns the latter procedure not always carried out . They concluded the necessity of harmonization of the practices for the management of birth with MSAF since the practice performed in these infants were very varied[44] .

Yoder et al[45] reported a progressive decrease in the incidence of MAS within the period of 9 year and attributed to this change in obstetrical practices .Meconium aspiration syndrome decreased nearly four-fold from 1990-1992 to 1997-1998 (5.8% to 1.5% of meconium-stained infants more than 37 weeks;P < .003). The only change in neonatal characteristics was a 33% decrease in births more than 41 weeks with a reciprocal 33% increase in births 38-39 weeks during 1997-1998. Significant changes in obstetric practice included more frequent diagnosis of non reassuring fetal heart rate patterns, greater use of amnioinfusion, and increased cesarean delivery rate in 1997-1998. By logistic regression analysis, the only consistent risk factor for meconium aspiration syndrome across all three epochs was the presence of tracheal meconium. Suctioning of the hypopharynx is not a risk free procedure . potential complication such as the delay in delivery of the infant and the onset of resuscitation efforts , damage to mouth and hyphopharynx , and cardiac arrythemias secondary to vagal stimulation may result from the practices.[7,28,39]

Methodology

A prospective quasi randomized control trial, assessor blind, single centre study was done at Department of obstetrics & gynecology , Geetanjali Medical College & hospital, Udaipur, Rajasthan. Patients were enrolled over a total period of 16 months started from July 2020 to October 2021. Inclusion criteria were (1) birth through MSAF of any consistency; (2) gestational age of 37 weeks or long and (3) cephalic presentation. Exclusion criteria were (1) major congenital malformations; (2) inability to randomize before delivery.

Waiver of consent approved by the institutional review boards on the grounds of the minimal risk assumption. Minimal risk is defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Infants born on odd dates underwent intervention of oropharyngeal and nasopharyngeal suction. Those born on even dates did not undergo that intervention. Neonatology resident whom were in charge of resuscitation in labor room were not in charge of subsequent patient care to avoid bias. The clinicians, who subsequently had

given care for the infant outside of the delivery room, were unaware of individual treatment group assignments and any trial results during the study

Procedure

In infants randomly allocated to the suction group, intrapartum suctioning had been undertaken with a suction peddle machine. In infants randomly allocated to the suction group, intrapartum suctioning was undertaken with an appropriately sized suction catheter (10-Fr to 13-Fr) connected to a negative pressure of 100 mm Hg. Oropharyngeal suctioning had been done first, followed by bilateral nasopharyngeal suctioning. This technique had been used in infants born both vaginally and by caesarean section. Thereafter, care had been given according to guidelines of the Neonatal Resuscitation Program of the American Academy of Pediatrics and the American Heart Association, which recommended tracheal suction followed by positive pressure ventilation only in the case of non–vigorous infants (Vigorous defined as strong respiratory efforts, good muscle tone, and a heart rate greater than 100 beats per min).[46]

Chest radiographs of all infants born through meconium stained amniotic fluid had been taken . Indications for mechanical ventilation were (1) paO2 less than 50 mm Hg or O2 saturation less than 92% in FiO2 more than 0·8, (2) pCO2 greater than 60 mm Hg, or (3) clinically significant apnoea or clinical deterioration as determined by the attending neonatologist. Diagnosis of the syndrome had been defined according to the working definition of the National Neonatal – Perinatal Database of India[46], defined as the presence of at least two of the following features with the history of MSAF: 1. Meconium staining of nails or umbilical cord or skin. 2. Respiratory distress soon after birth or within 1 hour of birth. 3. Radiological evidence of aspiration pneumonitis (with areas of atelectasis and / or hyperinflation)

Major secondary outcome variables were mortality; incidence of severe MAS (ie, need for mechanical ventilation); air leaks; occurrence of other disorders causing respiratory distress; and duration of oxygen treatment, mechanical ventilation, and hospital stay. Additionally, the recorded outcomes included (among others) Apgar scores, need for positive-pressure ventilation in the delivery room, pneumothorax, and other respiratory disorders.

Statistical analysis

We analyzed data on an intention-to-treat basis. For continuous variables, we used analysis of variance in normal distributions and the Mann-Whitney *U* test otherwise. Chi squire or Fisher's exact test was used for categorical items. Significance was assumed at the $p<0.05$ level.

Results

We conducted a prospective quasi-randomized controlled trial ,assessor blind single centre study to assess the effectiveness of Intrapartum Oropharyngeal and Nasopharyngeal suctioning compared with nonsuctioning in the prevention

of MAS and its complications at Department of obstetrics & gynecology , Geetanjali Medical College & hospital, Udaipur, Rajasthan.

Patient Population

This study was carried out over a total period of 16 months started from July 2020 to October 2021. 312 newborns were randomly allocated to receive suction (n=127) & no suction(n=185). In population characteristics(table1) there was statistically significant difference among maternal age, complications during the pregnancy , ultrasonography not done during antenatal period in suction and nonsuction group. There was no statistically significant difference among antenatal visits, gravidity and AFI in antenatal USG in suction and nonsuction group . There was statistically significant difference in mode of delivery , both in LSCS and vaginal delivery .

In newborn's details, in both group birth weight similar (2646.2gms in suction group Vs 2597.2 gms no suction group p = 0.377,) sex distribution were normal (p = 0.186) , gestational age wise distribution i.e term (120/127 in suction group Vs 179/185 in no suction group; p =0.486), postterm (7/127 in suction group Vs 6/185 no suction group; p=0.486), small for gestational age(31/127 in suction group vs 61/185 in nonsuction group), appropriate for gestational age same in both group (96/127 in suction group vs 124/185 in nonsuction group){ AGA vs SGA, p=0.133 } Low Birth Weight babies distribution similar(38/127 vs 62/127, p = 0.586) . But there were statistically significant difference in APGAR score at 1 minute and 5 minute ,20 babies had <7 APGAR score at 1 minute in suction group and 8 babies in non suction group (p=0.001) ,average apgar score at 1 minute had statistically significant difference in suction and nonsuction group (in suction group 7.8 +/-1.9 [mean , SD] in non suction group7.9+/-1.4 [mean , SD] p=0.012) apgar score at 5 minute (8.7+/-1.2 [mean , SD] vs 8.9+/-0.8[mean , SD] p=0.035) .Also endotracheal suction(in suction group 44/127 vs in non suction group 5/185, p< .00001) and positive pressure ventilation at the time of birth(32/127 in suction group vs 4/185 in non suction group p< .00001) both were significantly high in suction group compared to nonsuction group (table 2).

Incidence of MAS was similar in both groups ,in suction group 34 babies developed meconium aspiration syndrome(MAS) out of 127 whereas in nonsuction group 36 babies developed MAS (P =0.167).Intrapartum suctioning made no difference to the occurrence of MAS . Intrapartum suctioning also not made any difference in death or survival(death 5/127 in suction group and 5/185 in non suction group p=0.779), duration of hospital stay(4.2+/-3.3 days in suction group and 4.0+/-2.6 p=0.745). No baby developed pneumothorax in both group , only one baby developed pneumonia that was in non suction group. In both group occurrence of PPHN similar in both group (4/127 in suction group 3/185 in non suction group p=0.613). babies required inotropic support were similar in both group (3/127 in suction group and 3/185 in nonsuction group, p= 0.961). So that complications in both group similar (9/127 in suction group and 11/185 in non suction group p=0.881) . But there were statistically significant difference in need of respiratory support (25/127 in suction group 18/185 in nonsuction group p=.019), there were significantly more babies required mechanical ventilation(13/127 in suction group and 4/185 in non suction group p=0.005) .

though need of only 0_2 therapy in both group similar(12/127 in suction group 14/185 in nonsuction group p=0.167).

Table 1: Maternal Demographic Data

		Suction Group (mean)	*Nonsuction Group (mean)*	*P value*
Maternal Age		*25.4 (+4.1) yrs*	*21.4 (+3.4) yrs*	*0.000**
Antenatal visits		*4.2 (+2.8)*	*4.7 (+2.8)*	*0.196**
Gravida	Primigravidas	61/127 (48.04%)	95/185 (51.35%)	0.645**
	Multigravidas	66/127 (51.35%)	90/185 (48.65%)	
Complications in pregnancy	Yes	56/127 (44.09%)	59/185 (31.89%)	
	No	71/127 (55.91%)	126/185 (68.11%)	0.038**
AFI (USG)	Oligohydramnios (AFI<5)	11 /66 (16.67%)	14/131 (10.68%)	0.355**
	Adequate AFI	55 /66 (83.34%)	117/131 (89.31%)	
USG	Not done	61/127 (48.04%)	54 /185 (29.19%)	0.001**
	Done	66 127 (51.96%)	131/185 (70.81%)	
MSAF	Thick MSAF	81(63.78%)	88(47.57)	0.oo7**
	Thin MSAF	46(36.22%)	97(52.43%)	
Fetal distress	Yes	55(43.30)	84(45.40)	0.802**
	No	72(56.70)	101(54.60)	
Vaginal Delivery		56 (44.09%)	114(61.62%)	0.003**
Vaccume assisted		1 (0.78%)	0	0.850**
Forceps assisted		9 (07.09%)	14(07.56%)	0.952**
LSCS	*LSCS Emergency*	*56 (44.09%)*	*48 (25.94%)*	*0.001***
	LSCS Elective	*5 (3.95%)*	*9 (4.86%)*	*0.912***

Table 2 Newborn Demographic Data

		Suction group(%)	Nonsuction group(%)	P value
Sex	Male	69 (54.33%)	93(50.2%)	0.186**
	Female	93 (45.67%)	92(49.7%)	
Gestational age	AGA	96((75.60%)	124(67.03%)	0.133**
	SGA	31((24.40%)	61(32.97%)	
	Term	120((94.49%)	179(96.76%)	0.486**
	Post term	7(5.51%)	6(3.24%)	
Birth wt.	<2.5 kg	38(29.92%)	62(33.51)	0.586**
Birth wt. (gm) (Mean+ SD)		2646.2 (+491.2)	2597.2 (+472.0)	0.377*
Apgar score at 1 min	<7	20(15.7%)	8(4.3%)	0.001**
	>7	107(84.2%)	177(95.6 %)	
Apgar score at 1 min (Mean+ SD)		7.8 (+1.9)	7.9 (+1.4)	0.012***
Apgar score at 5 min (Mean+ SD)		8.7 (+1.2)	8.9 (+0.8)	0.035***
Et suction required		44(34. 6%)	5(2.7%)	0.000**
PPV required		32(25.2%)	4(2.2%)	0.000**

Table no 3: Outcomes

		Suction group (%)	Nonsuction group (%)	P value
MAS Yes		34(26.7%)	36(19.5%)	0.167**
No		93(73.2%)	149(80.5%)	
Only 02 therapy		12 (9.5%)	14 (7.56%)	0.702**
Ventilation		13(10.23%)	4 (2.20%)	0.005**
CPAP		0	0	----
Respiratory support	required	25 (19.7%)	18 (9.7%)	0.019**
	not required	*102 (80.3%)*	*167 (90.3%)*	
PPHN		*4 (3.14%)*	*3 (1.62%)*	*0.613***
Pneumothorax		*0*	*0*	----
Pneumonia		*0*	*1 (0.5%)*	*0.850***
Inotropic support required		*3 (2.36%)*	*3 (1.08%)*	*0.961***
Complications		*9 (7.9%)*	*11(5.9%)*	*0.881***
No complications		*117 (92.1%)*	*171 (92.4%)*	
Duration of hospital stay (days)		*4.2 (+3.3)*	*4.0 (+2.6)*	*0.745**
Death		*5 (3.9%)*	*5 (2.74%)*	*0.779***
Survival		*122 (96.1%)*	*180 (97.33%)*	

Unpaired t test / **Chi square test

Discussion

In our quasi randomized controlled trial assessor blind single centre study, of term-gestation infants born through MSAF, intrapartum suctioning did not decrease the incidence of MAS. Other important outcomes, including mortality, air leaks, length of hospital stay , persistent pulmonary hypertension, were similarly unaffected by this procedure. In our trial, in suction group significantly more infants required endotracheal suction and positive pressure ventilation at the time of delivery compared to infants in nonsuction group . Also there was statistically significant difference in need of mechanical ventilation, though need of only 0_2 therapy in both group similar .

Our study has similar findings as compared to other previous studies that assessed efficacy of intrapartum suction in prevention of meconium aspiration syndrome i.e Falcigia et al[34,35] , Vein et al[36.] In contrast to our study carson et al[28] and Wiswell et al [36] studies shown intrapartum suction has role in prevention in meconium aspiration syndrome. Carson et al [28] reported an incidence of MAS of 1.9% among 947 patients with a mortality rate of 28% during a period when only postdelivery intubation and suction was performed compared with an incidence of 0.4% among 273 patients (P = .07), and no deaths when intubation and suctioning was combined with intrapartum suctioning. There was a reduction in the number of cases and deaths due to MAS after the introduction of intrapartum suctioning, i.e. comparing the first period and the latter two periods, although this was not statistically significant.

By contrast, , nonrandomized clinical trial by Falciglia et al [34,35] compared early suctioning (suctioning by the obstetrician before delivery of the thorax) and late suctioning (suctioning by the obstetrician after delivery of the thorax) and showed no difference. In the first study, no differences in rate of meconium below the cords (36% versus 37%) or the incidence of MAS (20% in each group) between early and late suctioning were noted [34]. The second study reported a higher rate of meconium below the cords (53%) among the early suctioning group compared with the late suctioning group, which had a rate of 36% (P < .001), but there was no difference in the incidence of MAS between the two groups (P >.05) [35]. The reason for the differences in occurrence of meconium below the cords in the second study is unclear.

Falciglia et al.[34,35] reported results that were contrary to the findings by Carson et al[28]. First, in a retrospective analysis of morbidity and mortality data of patients born through MSAF, the authors reported that the timing of suction (i.e. whether the suction was performed before or after delivery of the chest) did not influence the presence of meconium below the vocal cords.[34]Second, in a prospective observational study, the authors reported that early (before delivery of the shoulders) oropharyngeal and nasopharyngeal suctioning at the perineum did not affect the rate of meconium aspiration syndrome.[35] Moreover, in the early group oropharyngeal and nasopharyngeal suctioning , 35% of the infants with MAS developed tension pneumothorax requiring chest drain.

A study by Wiswell et al [36] supported the use of intrapartum suctioning to reduce MAS when it reported on a subset analysis of a randomized controlled clinical trial. The incidence of MAS was 8.5% in infants who did not have intrapartum suction (n = 94) compared with 2.7% in infants who had intrapartum suction (n = 54; P = .013). Actually this study was done to see effect of endotracheal suctioning in vigours baby for prevention of meconium aspiration syndrome, which was the primary outcome of study, and effect of intrapartum suction in prevention of meconium aspiration syndrome was secondary outcome. Intrapartum suction done in 2000 babies and not done 90 babies only, so there was grossly unequal distribution in both the groups.

Recently, Vain et al.[37] in a large, multicenter, randomized study, reported that routine intrapartum oropharyngeal and nasopharyngeal suctioning of term infants born through MSAF does not prevent MAS. There were also no differences in subgroups of patients known to be at high risk of developing MAS. The subgroups included those with thick MSAF, abnormal fetal heart rate during labor, and those requiring extensive resuscitation in the delivery room. The study by Vain et al is the only large, randomized, clinical trial that has looked at intrapartum suctioning. This report provides the most conclusive evidence so far showing the failure of intrapartum suctioning to prevent MAS in the presence of MSAF. In this study total no. of patient 2514 , suction done in 1263 infants , not done in 1251 infants . There was no difference in incidence of MAS , in need of mechanical ventilation , and mortality.

Current recommendation by AAP through the neonatal resuscitation programme, the international Liaison committee on resuscitation (ILCOR), and the ACOG, intrapartum management of these pregnancies has radically changed.

Intrapartum suction of infants with MSAF is not recommended anymore [20,21,22]. Despite the evidence & recommendations, some authors still recommend intrapartum suction, if there is MSAF, specially for infants born in communities with limited resources, on the feeling that "the procedure is simple & does not carry significant adverse effects". They follow different strategy according to meconium consistency[23,24]. To base on feelings and assumptions such as a strong assertion – that intrapartum suction may be different in low resources population – is a rather weak argument ; feelings and expert opinion considered level of evidence 5 . Our study is carried out in tertiary care , referral hospital of Mumbai of low resource country , there major proportion of mother from middle and low socioeconomic status.

Suctioning of the hypopharynx is not a risk free procedure . Potential complication such as the delay in delivery of the infant and the onset of resuscitation efforts , damage to mouth and hyphopharynx , and cardiac arrythemias secondary to vagal stimulation may result from the practices.[7,28,39]
In our study significantly more infants required postdelivery endotracheal suction and positive pressure ventilation in suction group compare to nonsuction group, possible reason behind this is, the ratio of high risk mothers (having antenatal complications) was more in suction group than in nonsuction group & as mentioned above suctioning is also associated with delay in delivery and onset of resuscitation efforts of infant.

Conclusion

Routine intrapartum suctioning of infants born through MSAF does not reduce the incidence of MAS. On the contrary, intrapartum suctioning might result in complications like more baby required neonatal resuscitation and respiratory support .

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