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Randomized trials versus observational studies in adolescent pregnancy prevention

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Abstract

The objective of this study is to compare the results of randomized trials and observational studies of interventions to prevent adolescent pregnancy. We identified published and unpublished reports through computerized searches of CATLINE, CINAHL, CONFERENCE PAPERS INDEX, DISSERTATION ABSTRACTS ONLINE, EMBASE, ERIC, MEDLINE, NTIS, POPLINE, PsycINFO, and SOCIOLOGICAL ABSTRACTS; manual searches of eight relevant journals; reference lists from primary articles; and contact with content experts. We included randomized trials and observational studies that evaluated the impact of primary prevention interventions including sex education classes, school-based clinics, free-standing clinics, physician/nurse practitioner practice-based service, improved access, and community-based programs on four outcomes: sexual intercourse, birth control use, responsible sexual behavior, or pregnancy in adolescents. One investigator abstracted the data and a second conducted a detailed review of the abstraction. We identified 13 randomized trials and 17 observational studies. We generated estimates of the impact of the interventions separately for males and females for all four outcomes for both observational studies and randomized trials. For six of the eight outcomes the summary odds ratios for the observational studies showed a significant intervention benefit ($P < 0.05$) while the randomized trials did not show a benefit for any outcome in either females or males. The difference between the results of the observational studies and randomized trials was statistically significant in two of the eight outcomes ($P < 0.05$ for initiation of intercourse and pregnancy in females). Observational studies yield systematically greater estimates of treatment effects than randomized trials of adolescent pregnancy prevention interventions. Public policy or individual patient treatment decisions should be based on observational studies only when randomized trials are unavailable and only with careful consideration of possible biases.

Keywords: Randomized trials; Observational studies; Adolescent pregnancy; Prevention strategies

1. Introduction

Observational study designs are those in which patients' preferences, or the judgement of health care workers, determine whether study participants receive an experimental or control intervention. Observational studies contrast with randomized trials, in which allocation of patients according to chance minimizes bias attendant on known and unknown prognostic differences between treatment groups. When investigators have compared the results of randomized trials to those of observational studies they have generally [1–7], but not always [8,9], found larger effect sizes in the weaker designs. Nevertheless, health professionals continue to use observational studies as a basis for management decisions. This is appropriate if there are no other data on which to rely, though cognizance of the likely inflation of intervention effects remains important. When randomized trials are available, it seems appropriate that they form the basis of patient management.

We conducted a systematic review of studies of adolescent pregnancy prevention strategies. Initially, we included both randomized trials and observational studies, but made an a priori decision to explore study design as a possible determinant of outcome, and pool randomized trials separately if appropriate. We believe that, given clinicians' continued reliance on observational studies as a basis for management decisions (e.g., in determining use of postmenopausal hormone replacement therapy), exploring the effect of study design on outcome remains important. This is particularly germane in adolescent pregnancy prevention, an area in which recommendations for dissemination of prevention programs [10] have received wide attention. In this article, we report the impact of adolescent pregnancy prevention programs in randomized trials and observational studies.

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2. Methods

2.1. Eligibility criteria

We included randomized trials and observational studies focusing on adolescents 18 years of age or less, evaluating a variety of primary prevention programs including sex education classes, school-based clinics, free-standing clinics, physician/nurse practitioner practice-based service, improved access, and community-based programs. We included primary studies if they reported initiation of sexual intercourse, birth control use, or pregnancy and had been conducted in North America, Australia, New Zealand, United Kingdom, Europe (excluding Eastern Europe) or Scandinavia. We included both published studies and dissertations, conference proceedings, technical reports, and other unpublished documents that met our eligibility criteria. We performed all analyses separately by sex.

2.2. Search for primary articles

Our literature search extended from 1970 to May, 1993. We searched the following computerized data bases: CATLINE (CATalog onLINE), CINAHL (Cumulative Index to Nursing and Allied Health Literature), CONFERENCE PAPERS INDEX, DISSERTATION ABSTRACTS ONLINE, EMBASE, ERIC (Educational Resources Information Center), MEDLINE, NTIS (National Technical Information Services), POPLINE (POPulation information onLINE), PsycINFO (PSYCHOLOGICAL ABSTRACTS), and SOCIOLOGICAL ABSTRACTS (search strategies provided on request). We reviewed the reference lists of all papers for relevant citations. In addition, we reviewed the table of contents of the following journals for 1992 and 1993; *Family Planning Perspectives*, *Adolescence*, *Journal of Adolescent Health Care*, *American Journal of Public Health*, *Youth and Society*, *Journal of Adolescent Research*, *Journal of Early Adolescence*, and *Journal of Research on Adolescence*. If we found any relevant articles, we extended the hand search back to 1988.

Two individuals independently rated each citation in every search to determine whether it met eligibility criteria for retrieval. We retrieved any article that either rater thought, on the basis of the title, might be relevant to the overview. Once retrieved, we rated, independently and in duplicate, the relevance of the full manuscripts. Disagreement was resolved by consensus.

When all the relevant studies had been identified, we compiled a list for distribution to experts to review for completeness. At the time we were undertaking our work, three researchers in the United States were conducting reviews of similar literature and these experts reviewed our list for omissions.

2.3. Data extraction

For each outcome included in the studies, we ascertained the number who had and who had not experienced the outcome (i.e., initiation of sexual intercourse, consistent birth control use, responsible sexual behavior, and pregnancy) for the last follow-up period. The outcome "responsible sexual behavior" was created by combining the outcomes "initiation of sexual intercourse" and "consistent birth control use." One of us (A.D.) extracted the data; a second (G.H.G.) conducted a detailed review of the data. When we could not find the relevant data in the report, we contacted the first author. Each of the 15 authors we had to contact to obtain information for data abstraction responded to our request.

2.4. Analysis

We constructed two-by-two (2×2) tables [11] for each outcome in each study, and calculated the associated odds ratio (OR) [12]. For pooling the odds ratios, we chose a random effects model in which both within-study and between-study variability are considered in producing a weighted mean of the individual study estimates, weights being inversely proportional to the sampling variances [13]. We analyzed results separately for females and males for each of the four outcomes. We calculated confidence intervals around the pooled odds ratios.

To test for heterogeneity, the squared difference between the individual study OR and the summary OR was multiplied by the study weight and these were summed across all studies. The result of this calculation was compared to a chi-square distribution with the number of degrees of freedom equal to one less than the number of studies in the meta-analysis. We used a *Z*-score to generate a P-value related to the null hypothesis that there were no real differences in results from observational studies and randomized trials.

3. Results

We identified and retrieved a total of 1404 possibly relevant citations that were independently rated for relevance by two reviewers. The 1404 papers included 25 key reports which described a total of 30 studies that met our eligibility criteria: 13 randomized controlled trials [14–25] and 17 observational studies [22,26–38]. One report [16] included 2 randomized controlled trials, another one randomized trial and one cohort study [22], and a third [34] included 4 cohort studies. Of the 25, 6 were doctoral dissertations, 1 was a master's thesis, 2 were unpublished, 3 were chapters in textbooks, and 13 were published in journals.

Table 1 describes the 30 studies. The number of studies that examined each outcome by sex are as follows: initiation of sexual intercourse (females, 18 studies; males, 10 studies); consistent birth control use (females, 14 studies; males, 5 studies); responsible sexual behavior (females, 14 studies; males, 5 studies); pregnancy (females, 20 studies; males, 7 studies). Fourteen of the 18 studies that included sexual intercourse as an outcome restricted analysis of this variable to those who had not yet been sexually active before the intervention. However, the remaining four studies compared

Table 1
Description of studies that evaluate adolescent pregnancy prevention strategies

Author, year [reference #] (publication)	Setting	Design	Sample size/characteristics	Theoretical framework	Intervention	Length & success of follow-up	Outcome
Jay *et al.* 1984 [20] (published)	adolescent gynecology clinic in Georgia, US	RCT	57 females aged 14–19 from lower SES on OCs; 96.5% black	not specified	peer versus nurse counseling on adolescent compliance with OCs	4 months 66.7% followed	pregnancy
Herceg-Baron *et al.* 1986 [19] (published)	9 family planning clinics in Pennsylvania, US	RCT	417 female <16–17 year olds; 53% black	not specified	either 6 weekly 50-min counseling sessions or 2–6 telephone calls	15 months 85.9% followed	BC compliance responsible sexual behavior pregnancy
Handler 1987 [17] (dissertation)	2 public schools in Illinois, US	RCT	63 7th & 8th grade black females mean age of 13.3 years	knowledge-access-empowerment	**Peer Power Projec**t 1 hr per week during school year to increase knowledge, enhance decision-making skills	12 months 84.1% followed	Initiation of intercourse BC use responsible sexual behavior pregnancy
Slade 1989 [23] (dissertation)	high school in Washington, D.C.	RCT	201 10th–12th grade females all black; most living in female-headed households	not specified	**Life Outcome Perceptions** 1 hr session focusing on negative impact of early childbearing	2 months 90.0% followed	initiation of intercourse BC use responsible sexual behavior
Baker 1990 [14] (dissertation)	family planning clinic, New Jersey, US	RCT	62 sexually active 15–18 year old females from minority racial groups	cognitive behavioral theory	**Self-efficacy training** One 5.5-hr session on problem solving and communication	6 months 77.4% followed	initiation of intercourse OC compliance responsible sexual behavior pregnancy
Eisen *et al.* 1990 [15] (published)	6 family planning agencies & 1 school district in Texas, California, US	RCT	1444 13–19 year olds (67% 15–17 years) low income, inner-city youth, 53% Hispanic, 24% black	health belief model, social learning theory	**Teen Talk Program** 12–15 hr	12 months 61.5% followed	initiation of intercourse BC use responsible sexual behavior pregnancy
Hanna 1990 [18] (dissertation)	2 family planning clinics in a rural state in upper Midwest US	RCT	51 16–18-year-old never-married females seeking OCs for first time; 98% white	King's theory of nursing	nurse–client transactional intervention	3 months 76.5% followed	OC compliance responsible sexual behavior
Smith 1990 [24] (dissertation)	inner city high school in New York, US	RCT	120 freshman; 74% females; 43% blacks; 31% West Indian; 23% Hispanics	operant theory	**Teen Incentive Program** 8 weekly introductory sessions, 6-week career mentorship; 6-week life skills application sessions	6 months 79.2% followed	initiation of intercourse BC use responsible sexual behavior
Jorgensen 1991 [21] (published)	schools in Delaware, Mississippi, Ohio, US	RCT	136 7th grade 12–16 year olds; 50% females; 63% whites; >50% low income	not specified	**Project Taking Charge** 6-week abstinence & vocational education program	6 weeks 100% followed	initiation of intercourse

(continued)

Table 1 (*continued*)

Author, year [reference #] (publication)	Setting	Design	Sample size/characteristics	Theoretical framework	Intervention	Length & success of follow-up	Outcome
Thomas *et al*. 1992 [25] (published)	21 schools with Grades 7 & 8 in Ontario, Canada	RCT	3290 grade 7 & 8 students 51% females; majority white; range of income levels	cognitive-behavioral theory	**McMaster Teen Program** 10 sessions focusing on problem-solving, decision-making	4 years 83.9% to 3 years	initiation of intercourse BC use responsible sexual behavior pregnancy
Grossman & Sipe 1992 [16] (unpublished) Note: 2 separate randomized trials	5 cities in Massachusetts, California, Oregon, Washington, US	RCT	3226 14–15 year olds economically & educationally disadvantaged, 45% black, 18% Hispanics	not specified	**Summer Training & Education Program (STEP)** work experience, life skills during 2 summers	42 months (1 RCT), 54 months (1 RCT) 80.9% followed	pregnancy
Philliber & Allen 1992 [22] (published) Note: 2 studies	65 sites in US	RCT cohort	985 11–21 year olds; 70% females; 40% blacks, 13% Hispanics, 40% whites	not specified	**Teen Outreach Program** school-based small group discussion & involvement in volunteer service in the community; met once per week through school year	9 months 89.9% followed	pregnancy
Frappier 1981 [27] (MSc thesis)	2 high schools in Quebec, Canada	cohort	1100 13–17 year olds; 53% females; range of SES levels	not specified	40-min classes every week throughout school year (10 months)	10 months 100% followed	initiation of intercourse
Ralph & Edgington 1983 [35] (published)	youth clinic in Texas, US	cohort	comparison of teen birth rates among low-income, minority female teens	not specified	**Youth Clinic** provided teen health care during school hours	12 months % followed NA	pregnancy (live births)
Williams et al. 1985 [37] (unpublished)	East Tennessee, US	cohort	comparison of teen birth rates among females ages 11–18	not specified	**Appalachian Adolescent Health & Education Project** at least 1 50-min lecture/discussion session	12 months % followed NA	pregnancy (live births)
Gibson 1987 [28] (dissertation)	7 high schools in New York, US	cohort	588 black and Hispanic 12–19 year olds; 79% females	not specified	**Teen Choice Program** 1-2 semesters of small group activities	3 months 68% followed	initiation of intercourse BC use responsible sexual behavior
Vincent *et al*. 1987 [36] (published)	western portion of a county in South Carolina, US	cohort	14–17 year old females; 58% black; low income	social learning theory, diffusion theory	saturation of a community with pregnancy prevention messages	12 months % followed NA	pregnancy
Klaus *et al*. 1987 [32] (published)	7 US areas	cohort	231 15–17 year-old females; 35% blacks; range of income levels	not specified	**Fertility Awareness** taught rhythm and discussions re self-concept, relationships with peers	12 months 78% followed	initiation of intercourse pregnancy

(continued)

Table 1 (*continued*)

Author, year [reference #] (publication)	Setting	Design	Sample size/ characteristics	Theoretical framework	Intervention	Length & success of follow-up	Outcome
Christopher & Roosa 1990 [26] (published)	3 community sites & 5 schools, Arizona, US	cohort	320 low-income, minority 6th-7th graders, 69% Hispanics, 21% black	not specified	**Success Express Program** 5-session program about abstinence	6 weeks 63.4% followed	initiation of intercourse
Howard & McCabe 1990 [29] (published)	53 schools in Georgia, US	cohort	536 male & female 8th grade 13–14 year olds from low-income families; 99% black	social influence theory	**Postponing Sexual Involvement** peer-led 10-session groups	12–18 months 100% followed	initiation of intercourse pregnancy
Moberg & Piper 1990 [33] (published)	2 schools in Wisconsin, US	cohort	265 8th grade 12–14 year olds; 55% females; no minority groups	social influence theory	**Project Model Health** 32-hr program on nutrition, sexuality, drug use	20 months 74.3% followed	initiation of intercourse
Kirby *et al*. 1991 [30] (published)	23 classes in 13 high schools in California, US	cohort	1033 grades 9–12 students; 53% females; 62% whites; 20% Hispanics	social influence, social learning theory, cognitive-behavioral	**Reducing the Risk** 15 sessions, strategies to resist pressures to have sex	18 months 73.4% followed	initiation of intercourse BC use responsible sexual behavior pregnancy
Kirby *et al*. 1991 [31] (published)	6 schools in: Indiana, California, Michigan, Mississipi, Florida, Texas, US	cohort 4 sites before/after, 2 sites	9th–12th graders; 54% females; 95% blacks; low income	not specified	school-based primary health care clinics that provided comprehensive health services	24 months % followed not applicable	initiation of intercourse BC use responsible sexual behavior pregnancy
Winter & Breckenmaker 1991 [38] (published)	6 nonmetropolitan family planning clinics in Pennsylvania, US	cohort	1261 females, <18 years of age making an initial or annual clinic visit; majority white	not specified	counseling, one-to-one education, reassurance & social support	12 months 38% followed	BC use responsible sexual behavior pregnancy
Nicholson & Postrado 1992 [34] (published) Note: 4 studies	Texas, Tennessee, Nebraska, Delaware, US	cohort	343 females aged 12–15 years; >80% blacks	not specified	**Growing Together** 5 2-hr sessions for parent-daughter pairs to improve communication **Will Power/Won't Power** 6 2-hr sessions focusing on assertiveness skills, peer pressure **Taking Care of Business** 9 2-hr sessions to encourage abstaining or using BC **Health Bridge** linking with comprehensive health clinics	24 months % followed not provided	initation of intercourse BC use responsible sexual behavior pregnancy

the number who were sexually active regardless of whether they had initiated sexual activity prior to the intervention. Eleven of the 14 studies that included birth control use as an outcome asked about use of birth control at all sexual encounters since the intervention with responses usually ranging from always used to never used. The remaining three studies asked about birth control use at the last time they had intercourse. Eighteen of the 20 studies that included pregnancy as an outcome asked about any pregnancy while two studies asked about live births only.

Table 2 summarizes the pooled estimates for all outcomes in females and Table 3 in males. In females, the pooled estimates suggest a positive intervention effect for initiation of intercourse and trends in favor of intervention in the other three outcomes. There is substantial heterogeneity in results across studies for all four outcomes ($P < 0.10$ in the test for heterogeneity). For all four outcomes, the observational studies suggest a statistically significant moderate positive intervention effect while the randomized trials suggest equivalence between intervention and control. The difference in results according to study design is statistically significant ($P < 0.05$) for initiation of intercourse and pregnancy.

Among the males, the pooled estimates do not suggest intervention effects for any outcome (Table 3). There is substantial heterogeneity in results across studies for three of the four outcomes ($P < 0.10$ in the test for heterogeneity). The observational studies suggest a statistically significant positive moderate intervention effect for initiation of intercourse and responsible sexual behavior. The randomized trials show a nonsignificant trend in favor of intervention for initiation of intercourse and weak trend in favor of control in responsible sexual behavior.

4. Discussion

This overview met rigorous methodologic criteria including explicit eligibility criteria, an exhaustive search of the literature, and highly successful efforts to identify unpublished studies. We successfully contacted authors to confirm or to request the data required for analysis and conducted all our analyses separately by sex.

Tables 2 and 3 present the key data from our analyses. We examined the effects of adolescent pregnancy prevention programs on four outcomes in both females and males. The pooled estimate from the observational studies suggested moderate, statistically significant intervention effects for six of the eight outcomes. The randomized trials did not show statistically significant effects for any outcome and showed an appreciable trend in favor of intervention in only one comparison. The differences in results according to study design were statistically significant in two of the eight comparisons. Were one relying on the results of the observational studies and using conventional levels of statistical significance, one would conclude that, as a group, adolescent pregnancy prevention programs had a positive effect on decreasing initiation of sexual intercourse, increasing birth control use and responsible sexual behavior, and reducing pregnancy in females, and on decreasing initiation of intercourse and increasing responsible sexual behavior in males. Were one relying on results from randomized trials, one would conclude that the evidence does not support a positive effect of the interventions on any outcome in either males or females.

The likely explanation for these results is that adolescents assigned to the interventions in observational studies were destined to have more positive outcomes than control adolescents irrespective of the intervention. One obvious example comes from an observational study [34] in which the investigators assigned adolescents who declined participation in the intervention to the control group. In general, it is likely that adolescents who received the intervention in observational studies were more predisposed to refrain from intercourse and, when sexually active, use birth control.

An alternative explanation of our findings is that the cohort studies evaluated more intensive or effective interventions which were truly of more benefit. Perusal of Table 1, however, reveals that the interventions mounted in the ran-

Table 2
Pooled estimates of intervention impact in females

	Initiation of intercourse[a]	Pregnancy[a]	Responsible sexual behavior[b]	Birth control use[b]
Number of randomized trials	7	9	8	8
Number of observational studies	11	11	6	6
Test for heterogeneity of results: P-value	0.003	0.001	0.07	0.06
Pooled random effects odds ratio—all studies (95% confidence intervals)	0.78 (0.62–0.99)	0.86 (0.71–1.03)	1.18 (0.98–1.42)	1.21 (0.98–1.50)
Pooled odds ratio—randomized trials	1.09 (0.90–1.32)	1.08 (0.91–1.27)	1.01 (0.75–1.36)	0.99 (0.64–1.54)
Pooled odds ratio—observational studies	0.64 (0.44–0.93)	0.74 (0.56–0.98)	1.27 (1.10–1.46)	1.38 (1.18–1.60)
Test for difference in pooled odds ratios between designs (P-values)	0.01	0.02	0.18	0.17

[a]Odds ratios greater than 1 indicate an undesirable effect of the intervention.
[b]Odds ratios greater than 1 indicate a desirable effect of the intervention.

Table 3
Pooled estimates of intervention impact in males

	Initiation of intercourse[a]	Pregnancy[a]	Responsible sexual behavior[b]	Birth control use[b]
Number of randomized trials	4	4	3	3
Number of observational studies	6	3	2	2
Test for heterogeneity of results: P-value	0.00002	0.45	0.0005	0.03
Pooled random effects odds ratio—all studies (95% confidence intervals)	0.77 (0.53–1.13)	0.88 (0.74–1.04)	1.06 (0.73–1.54)	0.94 (0.68–1.29)
Pooled odds ratio—randomized trials	0.81 (0.35–1.90)	0.97 (0.62–1.51)	0.94 (0.55–1.60)	0.91 (0.71–1.18)
Pooled odds ratio—observational studies	0.71 (0.52–0.98)	0.85 (0.68–1.06)	1.21 (1.04–1.42)	0.82 (0.35–1.91)
Test for difference in pooled odds ratios between designs (P-values)	0.78	0.60	0.37	0.81

[a]Odds ratios greater than 1 indicate an undesirable effect of the intervention.
[b]Odds ratios greater than 1 indicate a desirable effect of the intervention.

domized trials and observational studies were very similar in their nature and intensity. Although few interventions were identical, there was considerable overlap among many. In one way of classifying the programs, two observational studies undertook abstinence counseling (5 and 10 hr) [26,29] as did one randomized trial (6 hr) [21]. Investigators mounted programs combining education and group discussion in 10 cohort studies (from 1 to 40 hr) [22,27,28,30,32–34,37] and 5 randomized trials (from 1 to 40 hr) [15,17,22,23,25]. Five observational studies and one randomized trial provided counseling within the setting of birth control clinics in which the dose of the intervention is difficult to quantify, though in most cases appeared to be only a few minutes during each clinic visit. One observational study was unique in providing a community intervention targeted primarily at parents, teachers, and professionals. Two randomized trials were unique in providing 380 hr of work experience; three randomized trials (4 to 20 hr) [19,20,24], but no observational studies, focused on counseling interventions. In another way of classifying the interventions 4 [16,22,24] of 13 randomized trials and 2 [22,36] of the 17 observational studies involved multifaceted interventions.

Data from Table 1 also address two other alternative explanations of the findings. It is possible that if the studies were conducted during different periods of time, secular changes in pregnancy rates could have influenced the findings. As it turns out, the distribution of years in which the work was completed is very similar in the two groups of studies: of the 13 randomized trials, 4 were completed before 1990, 4 during 1990, and 5 after 1990; of the 17 observational studies, 6 were completed before 1990, 3 during 1990, and 8 after 1990. It is also possible that different durations of follow-up were responsible for differences in effectiveness. Once again, however, distributions are similar: of the 13 randomized trials, follow-up continued for 1 year or less in 9 and greater than 1 year in 4; of the 17 observational studies, follow-up continued for 1 year or less in 9, and greater than 1 year in 8.

Our results pertain only to studies completed by May, 1993. We are in the process of updating our meta-analysis. Because the analysis we have presented in this article suggests a biased assessment of outcome in observational studies, we concluded it was not worth the resource expenditure to repeat the analysis including observational studies conducted since 1993 and are restricting the analysis to randomized trials.

Our results emphasize the caution with which clinicians and health policymakers should view the results of observational studies. Health researchers do not always exercise such caution. Two recent overviews of adolescent pregnancy prevention have based their conclusions on the results of observational studies, and concluded that the programs produce beneficial effects on important outcomes [10,39]. One of these [10] received wide public attention in the United Kingdom and was considered key data for public health policy.

Researchers and policymakers are much more likely to attend to published studies than those that remain unpublished. Of the studies in our overview, 6 of 13 RCTs and 14 of 17 observational studies were published. The risk of overreliance on the results of observational studies may increase when the volume of published observational studies is appreciably greater than that of RCTs. Appropriate attention to study design is likely to have a particularly large impact on conclusions under these circumstances.

When resources for health interventions are limited and there are many effective interventions available, resources may be wasted if they are channeled into ineffective health management programs. Wherever possible, recommendations should flow from the results of randomized trials. When they have both randomized trials and observational studies available, clinicians and health policymakers would be wise to make inferences on studies using the stronger design. Further research and exploration is required to determine when, if ever, we can be confident of treatment effects when we have only observational studies to guide us.

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